In September 2021 Moderna tasked a new company, National Resilience, with making thier Covid-19 Vaccines. Resilience is back by by CIA investment company In-Q-Tel

moderna

Resilience to Manufacture mRNA for Moderna's COVID-19 Vaccine

September 8, 2021

SAN DIEGO & CAMBRIDGE, Mass.--(BUSINESS WIRE)--National Resilience, Inc. (Resilience), a company seeking to build the world's most advanced biopharmaceutical manufacturing ecosystem, and Moderna, Inc. (Nasdaq: MRNA), a biotechnology company pioneering messenger RNA (mRNA) medicines, today announced an agreement to manufacture drug substance for the Moderna COVID-19 vaccine.

Under the terms of the multi-year agreement, Resilience will produce mRNA for the Moderna COVID-19 vaccine at its facility in Mississauga, Ontario in Canada, for distribution worldwide.

"Moderna's COVID-19 vaccine has saved countless lives, and we're excited to manufacture mRNA for this important vaccine," said Rahul Singhvi, Sc.D, Chief Executive Officer of Resilience. "This collaboration has the potential to ensure more people are protected around the world from the deadly COVID-19 virus."

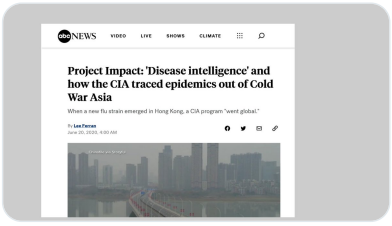
Separately, Moderna recently announced a collaboration to bring mRNA manufacturing to Canada through a Memorandum of Understanding (MoU) with the government of Canada to build a state-of-the-art messenger RNA (mRNA) vaccine manufacturing facility in the country including access to Moderna's mRNA development engine. The goals of this MoU are to build the foundation to support Canada with direct access to rapid pandemic response capabilities and to provide access to Moderna's vaccines in development for respiratory viruses.

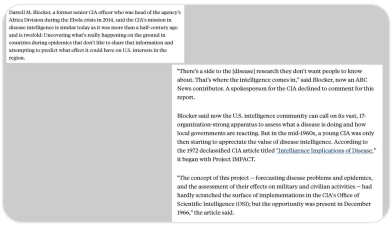
Destiny Rezendes @dezzie_rezzie

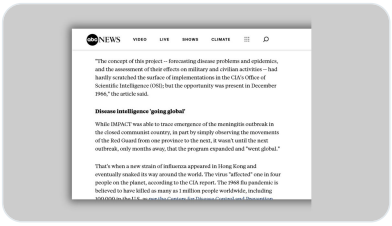
Jun 25 · 30 tweets · dezzie_rezzie/status/1672811608911872001

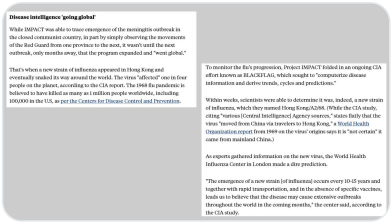
1 🧵"Those who forget history are condemned to repeat it"- George Santayana. A fitting quote for the story of Covid-19. Decades of American history has been forgotten, and surreptitiously obscured. The origins of C19 started not in 2019 but in the 1960's.

2🧵In 1966 an outbreak of meningitis hit the Guangdong Province of China. The outbreak caused the healthcare system and other governmental organizations started to crumble in China as a result of the strain. The CIA noticed this and began tracking diseases .

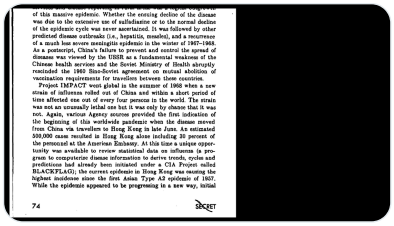








3🧵The CIA's reasoning was that disease outbreaks could create national instability so getting intel on disease spread became a matter of national security. The program was called PROJECT BLACKFLAG. From that program a global disease surveillance operation began...


of this massive epidemic. Whether the coming decline of the disease was due to the extensive use of sulfadiazine or to the normal decline of the epidemic cycle was never ascertained. It was followed by other predicted disease outbreaks (i.e., hepatitis, measles), and a recurrence of a much less severe meningitis epidemic in the winter of 1967–1968. As a postscript, China's failure to prevent and control the spread of diseases was viewed by the USSR as a fundamental weakness of the Chinese health services and the Soviet Ministry of Health abruptly rescinded the 1960 Sino-Soviet agreement on mutual abolition of vaccination requirements for travellers between these countries.

Project IMPACT went global in the summer of 1968 when a new strain of influenza rolled out of China and within a short period of time affected one out of every four persons in the world. The strain was not an unusually lethal one but it was only by chance that it was not. Again, various Agency sources provided the first indication of the beginning of this worldwide pandemic when the disease moved from China via travellers to Hong Kong in late June. An estimated 500,000 cases resulted in Hong Kong alone including 20 percent of the personnel at the American Embassy. At this time a unique opportunity was available to review statistical data on influenza (a program to computerize disease information to derive trends, cycles and predictions had already been initiated under a CIA Project called BLACKFLAG); the current epidemic in Hong Kong was causing the highest incidence since the first Asian Type A2 epidemic of 1957. While the epidemic appeared to be progressing in a new way, initial

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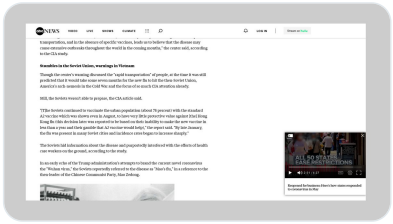
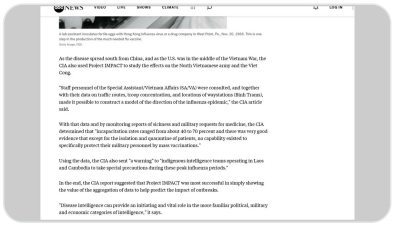
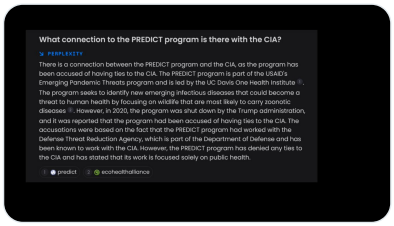
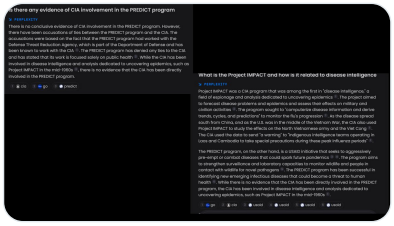
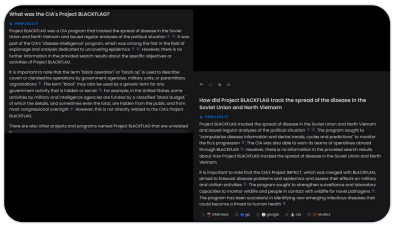


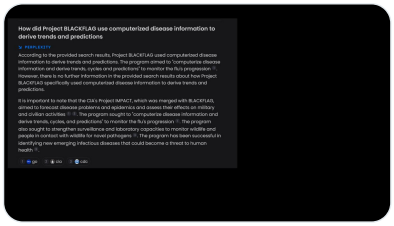


4🧵..and in 1968 the program was called Project IMPACT. IMPACT became a higher priority when China was struck with disease again with the 1968/1969 Hong Kong Flu, (at the time referred to as Mao's Flu/ Influenza A2/68) which swept thru the planet killing between 1-4 Million.







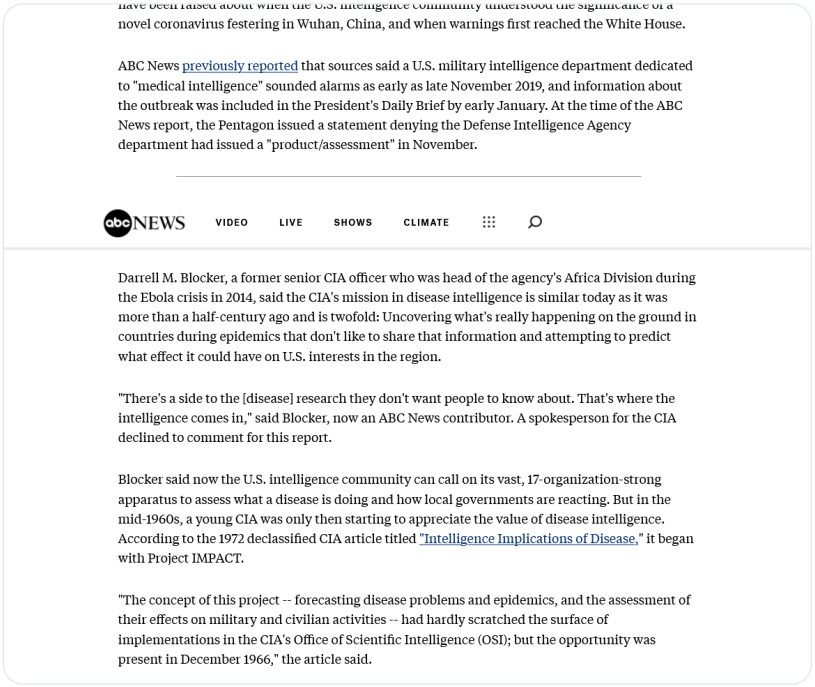


🧵5 HK Flu went on to claim over 100,000 US lives when our population was only 1/3 what it is today. BLACKFLAG & IMPACT used their intelligence resources in an attempt to slow the spread and to be an early warning system for US interests; deployed to China, Vietnam, and Russia.

6🧵 Prior to the CIA's bio-intelligence operations, in September of 1961, president John F Kennedy signed the Foreign Assistance Act which created the United States Agency for International Development of USAID program. Nixon later put a halt on biological experiments in 1969

7🧵 Biological Weapons programs started in 1943, following president Roosevelt's orders to stockpile bioweapons. A program which lasted 27 years *on paper.* Nixon's cancellation of the programs was a big hit for scientists, chemical producers as well as Project IMPACT

8🧵In a quiet ABC article from 2020 covering a part of this story, a former CIA senior officer, Darrell M. Blocker, spoke about PROJECT IMPACT saying, "There's a side to the [disease] research they don't want people to know about. That's where the intelligence comes in"



have been raised about when the U.S. intelligence community understood the significance of a novel coronavirus festering in Wuhan, China, and when warnings first reached the White House.

ABC News previously reported that sources said a U.S. military intelligence department dedicated to "medical intelligence" sounded alarms as early as late November 2019, and information about the outbreak was included in the President's Daily Brief by early January. At the time of the ABC News report, the Pentagon issued a statement denying the Defense Intelligence Agency department had issued a "product/assessment" in November.

abcNEWS VIDEO LIVE SHOWS CLIMATE

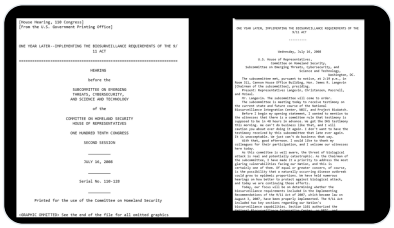
Darrell M. Blocker, a former senior CIA officer who was head of the agency's Africa Division during the Ebola crisis in 2014, said the CIA's mission in disease intelligence is similar today as it was more than a half-century ago and is twofold: Uncovering what's really happening on the ground in countries during epidemics that don't like to share that information and attempting to predict what effect it could have on U.S. interests in the region.

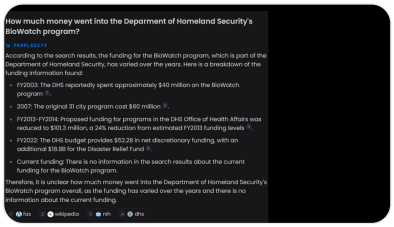
"There's a side to the [disease] research they don't want people to know about. That's where the intelligence comes in," said Blocker, now an ABC News contributor. A spokesperson for the CIA declined to comment for this report.

Blocker said now the U.S. intelligence community can call on its vast, 17-organization-strong apparatus to assess what a disease is doing and how local governments are reacting. But in the mid-1960s, a young CIA was only then starting to appreciate the value of disease intelligence. According to the 1972 declassified CIA article titled "Intelligence Implications of Disease," it began with Project IMPACT.

"The concept of this project -- forecasting disease problems and epidemics, and the assessment of their effects on military and civilian activities -- had hardly scratched the surface of implementations in the CIA's Office of Scientific Intelligence (OSI); but the opportunity was present in December 1966," the article said.

9🧵It's not everyday that I'd say I'd agree with a CIA agent, but in this instance I think he's right on the money. Despite the ban on bio weapons, surveillance wasn't banned, in-fact there was a new need to increase global surveillance, cue the disaster...



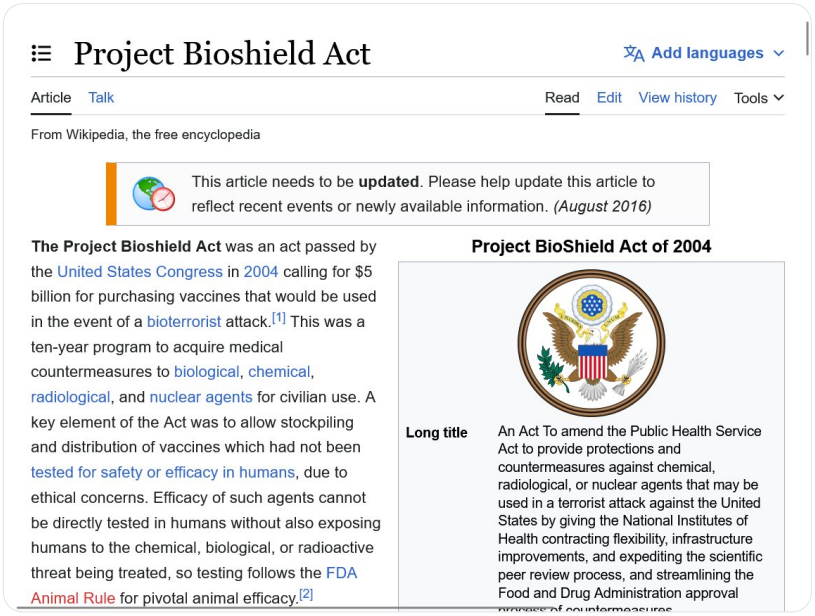


10🧵The cold war wasn't cold enough but fortunately for the rapacious Military Industrial Complex, 9/11 & subsequent anthrax attacks created all the excuses needed to step back into world & the business of biological weapons & surveillance.

Homeland Security

In response to the 2001 anthrax attacks, the President and Congress established the BioWatch Program (BioWatch) in 2003.[1] The program embarked on an aggressive effort to deploy a nationwide system to surveil for aerosolized exposure caused by the intentional release of biological agents. This system was initiated in 30 of the most populous cities within the United States. After the creation of DHS, BioWatch was initially established under the Science and Technology Directorate, and in 2007 was transferred to DHS' Office of Health Affairs. Then, in 2018, BioWatch transferred to DHS' Countering Weapons of Mass Destruction (CWMD) office with a budget averaging $76 million per fiscal year from 2018 to 2020.[2]

11 🧵 It wasn't important that Colin Powell sat before congress and bold face lied about the origins of the Anthrax used against policymakers after 9/11. What was important was the fear was set and a response was demanded. The answer? Project Bioshield Act and the creation of...



Project Bioshield Act

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From Wikipedia, the free encyclopedia

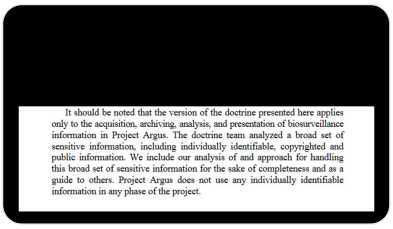
This article needs to be **updated**. Please help update this article to reflect recent events or newly available information. *(August 2016)*

The Project Bioshield Act was an act passed by the United States Congress in 2004 calling for $5 billion for purchasing vaccines that would be used in the event of a bioterrorist attack.[1] This was a ten-year program to acquire medical countermeasures to biological, chemical, radiological, and nuclear agents for civilian use. A key element of the Act was to allow stockpiling and distribution of vaccines which had not been tested for safety or efficacy in humans, due to ethical concerns. Efficacy of such agents cannot be directly tested in humans without also exposing humans to the chemical, biological, or radioactive threat being treated, so testing follows the FDA Animal Rule for pivotal animal efficacy.[2]

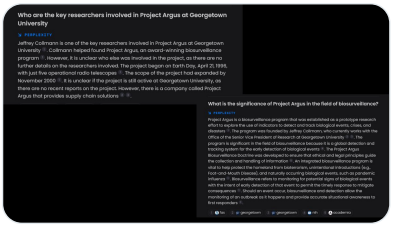
Project BioShield Act of 2004

Long title An Act To amend the Public Health Service Act to provide protections and countermeasures against chemical, radiological, or nuclear agents that may be used in a terrorist attack against the United States by giving the National Institutes of Health contracting flexibility, infrastructure improvements, and expediting the scientific peer review process, and streamlining the Food and Drug Administration approval

12 🧵 ..the Department of Homeland Security. It wasn't long before DHS started where the CIA had left off. W/ the intense scrutiny the CIA had suffered, the new shiny DHS was a PR dream come true-continuing the bio-warfare surveillance/ covert intelligence gathering



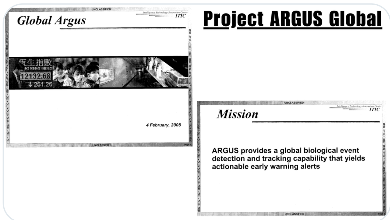
It should be noted that the version of the doctrine presented here applies only to the acquisition, archiving, analysis, and presentation of biosurveillance information in Project Argus. The doctrine team analyzed a broad set of sensitive information, including individually identifiable, copyrighted and public information. We include our analysis of and approach for handling this broad set of sensitive information for the sake of completeness and as a guide to others. Project Argus does not use any individually identifiable information in any phase of the project.



Who are the key researchers involved in Project Argus at Georgetown University

What is the significance of Project Argus in the field of biosurveillance?

13🧵Originally, the bio-surveillance programs, now entrusted to DHS, appeared under the name Project ARGUS GLOBAL which created the still active BioWatch program. ARGUS wasn't solely in the hands of DHS but partnered with Georgetown University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Project ARGUS Global
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Mission
ARGUS provides a global biological event detection and tracking capability that yields actionable early warning alerts
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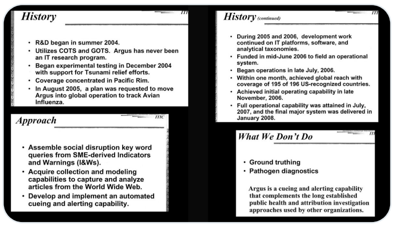
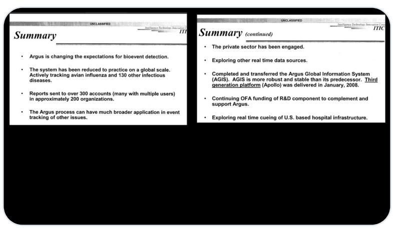

History
• R&D began in summer 2004.
• Utilizes COTS and GOTS. Argus has never been an IT research program.
• Began experimental testing in December 2004 with support for Tsunami relief efforts.
• Coverage concentrated in Pacific Rim.
• In August 2005, a plan was requested to move Argus into global operation to track Avian Influenza.
Approach
ITIC
• Assemble social disruption key word queries from SME-derived Indicators and Warnings (I&Ws).
• Acquire collection and modeling capabilities to capture and analyze articles from the World Wide Web.
• Develop and implement an automated cueing and alerting capability.
History (continued)
• During 2005 and 2006, development work continued on IT platforms, software, and analytical taxonomies.
• Funded in mid-June 2006 to field an operational system.
• Began operations in late July, 2006.
• Within one month, achieved global reach with coverage of 195 of 196 US-recognized countries.
• Achieved initial operating capability in late November, 2006.
• Full operational capability was attained in July, 2007, and the final major system was delivered in January 2008.
What We Don't Do
• Ground truthing
• Pathogen diagnostics
Argus is a cueing and alerting capability that complements the long established public health and attribution investigation approaches used by other organizations.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Summary
• Argus is changing the expectations for bioevent detection.
• The system has been reduced to practice on a global scale. Actively tracking avian influenza and 130 other infectious diseases.
• Reports sent to over 300 accounts (many with multiple users) in approximately 200 organizations.
• The Argus process can have much broader application in event tracking of other issues.
UNCLASSIFIED
Intelligence Technology Innovation Center
ITIC
Summary (continued)
• The private sector has been engaged.
• Exploring other real time data sources.
• Completed and transferred the Argus Global Information System (AGIS). AGIS is more robust and stable than its predecessor. Third generation platform (Apollo) was delivered in January, 2008.
• Continuing OFA funding of R&D component to complement and support Argus.
• Exploring real time cueing of U.S. based hospital infrastructure.


Chapter 2

DESIGNING ETHICAL PRACTICE IN BIOSURVEILLANCE

The Project Argus Doctrine

JEFF COLLMANN[1,*] and ADAM ROBINSON[2]

CHAPTER OVERVIEW

Biosurveillance entails the collection and analysis of information needed to provide early warning of outbreaks of infectious disease, both naturally occurring and intentionally introduced. Data derived from repositories containing various types of sensitive information may be required for this purpose, including individually identifiable, copyrighted, and proprietary information. The Project Argus Biosurveillance Doctrine was developed to ensure that ethical and legal principles guide the collection and handling of such information. Project Argus does not, however, use individually identifiable information or any material derived from individually identifiable information for any phase of the project. Further, Project Argus is not used for purposes of law enforcement, counterterrorism, or public health surveillance. This chapter details why and how the doctrine was developed and summarizes its guiding principles and key elements.

Keywords: Biosurveillance; Sensitive information; Information protection; Privacy

[1*] *O'Neill Institute for National and Global Health Law, Disease Prevention and Health Outcomes, School of Nursing and Health Studies, Georgetown University Medical Center, Box 571107, 3700 Reservoir Rd, NW, Washington, DC 20057–1107, USA, collmanj @georgetown.edu*
[2] *The MITRE Corporation, 7515 Colshire Drive, McLean, VA 22102, USA*

D. Zeng et al. (eds.), *Infectious Disease Informatics and Biosurveillance,* 23
Integrated Series in Information Systems 27, DOI 10.1007/978-1-4419-6892-0_2,

2. BACKGROUND

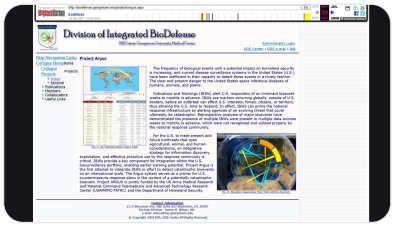
Project Argus developed the technical and doctrinal requirements for an integrated, multisource information system designed to perform global bio-

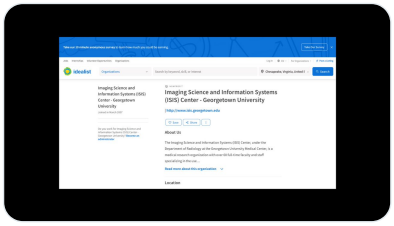
2. Designing Ethical Practice in Biosurveillance 25

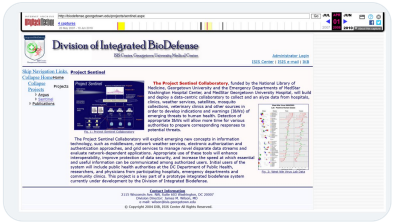
surveillance for epidemics; biological accidents; and bioattacks on humans, animals, and plants [1].

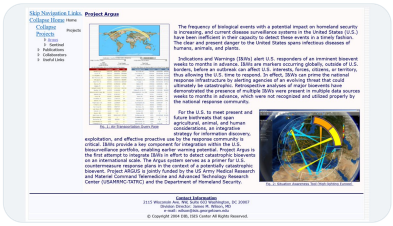
The ethical issues surrounding the development and maintenance of such a system have been a key consideration from the outset of Project Argus. No single public law or set of regulations governs the handling and protection of the broad range of sources, types, security classifications, and potential uses of the information to be collected and analyzed. Therefore, the Project Argus doctrine team was formed to develop the necessary guidance. The resulting biosurveillance doctrine sets forth explicit principles, management structures, policies, procedures, and technical design requirements intended to ensure the ethical handling and use of sensitive information by project participants. In this respect, a strong moral, organizational, and technical divide exists between Project Argus and initiatives that have drawn the censure of Congress, the media, and the American public for their failure to ensure such protections. After describing the methods used to develop the doctrine, we provide a high-level view of its guiding principles and key elements.

14 🧵 Georgetown University (GU,) much like Johns Hopkins, has a Center for Global Health Security, which once had a program called ISIS, & their Division of Integrated BioDefense which ran Project Argus alongside DHS, CIA, and USAMRIID.

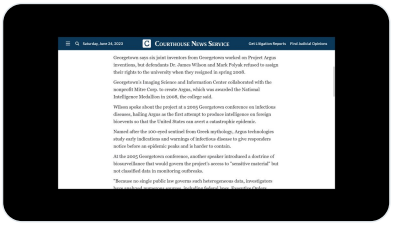


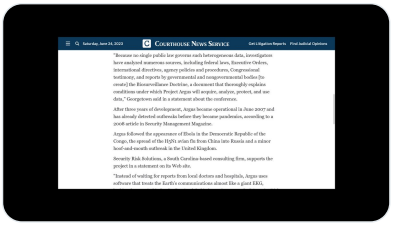


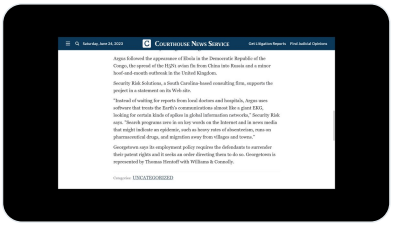




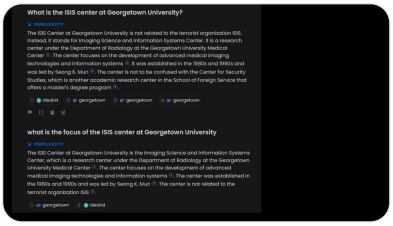
15🧵All went well for many years until GU sued two employees who refused to give up their patent rights for their technology that hosted ARGUS. The Mitre Corp was backed by GU in the fight for the ARGUS rights.

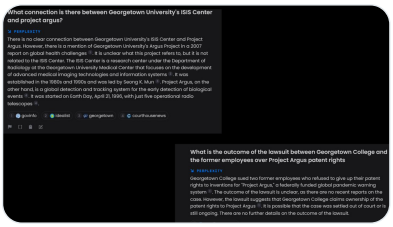




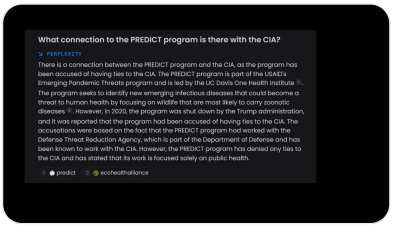


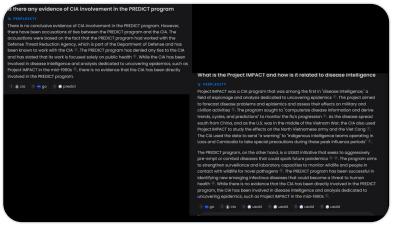
16🧵According to Courthouse News Service in a 2009 article, the contesting scientists were Dr. James Wilson & Mark Polyak. Little on the story can be found for how the case was resolved but GU's involvement in ARGUS wasn't over just yet.





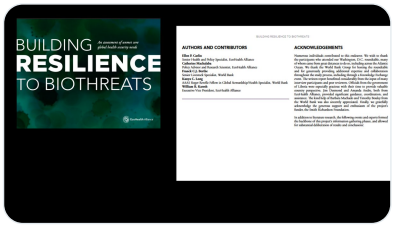
17🧵 When researching all of this, dozens of references pointed to the notion that USAID throughout the years had become a CIA front w/ the intention of foreign intelligence gathering as was all the biological programs and other countries began turning away the aid.



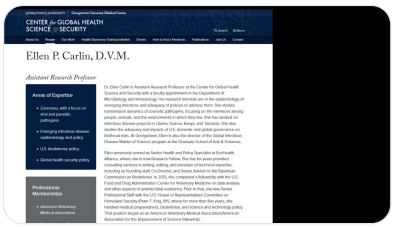


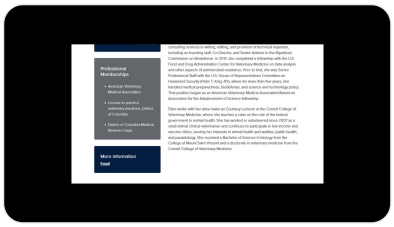
18🧵 The CIA had to bank on the long standing fact that despite any and all quarrels amongst countries that there was one avenue that remained open without question, and that was Science. Proof of this is seen in our collaboration with China & Russia in the ISS.

19🧵What better way to infiltrate hostile countries than to gather intelligence through the humanitarian efforts of globally beneficial science? So USAID continued its efforts and Georgetown stayed on the policy side of the matter.

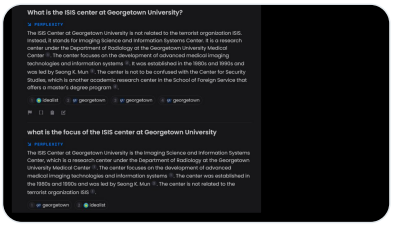


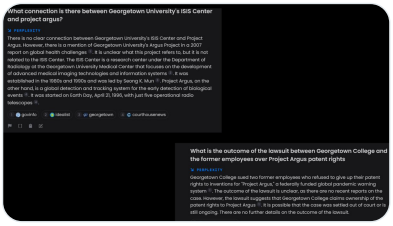
20🧵Yes, EcoHealth Alliance was funded through USAID, and DHS's countering WMD's office but they are also still tied to GU. In fact the USG has turned to GU for bio-security advice. The most recent policy papers on the matter featured two GU faculty authors..

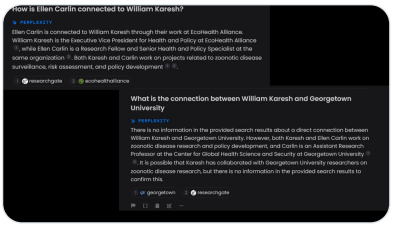


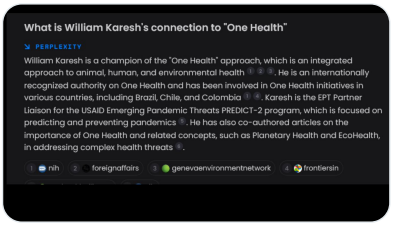


21🧵Ellen Carlin & William Karesh. Names that if you've followed my research closely you'll recognize as key members of EcoHealth Alliance. In fact it was Karesh who coined the term "One Health"

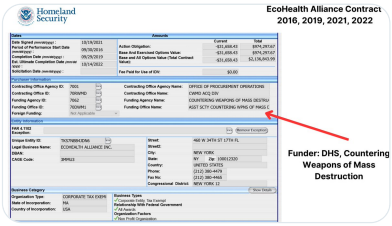


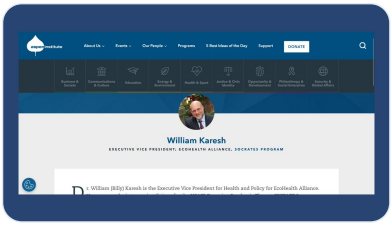


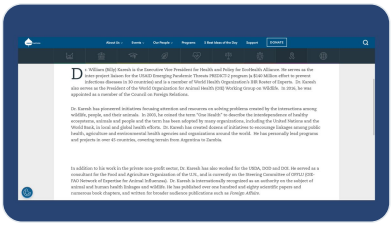




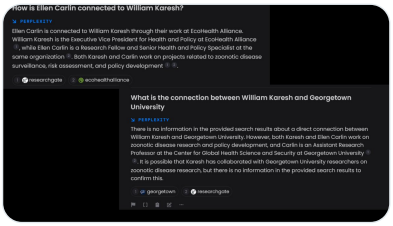
22🧵 "One Health" as I've covered before is a big NWO buzzword that can be found adopted by the; CDC, WHO, UN, and most importantly, UC Davis- the parent of the USAID PREDICT/PREVENT program and home to the One Health Institute.

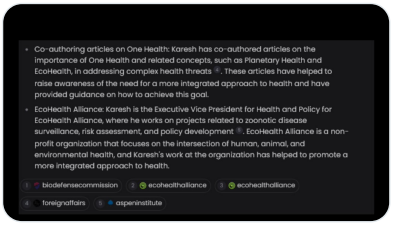


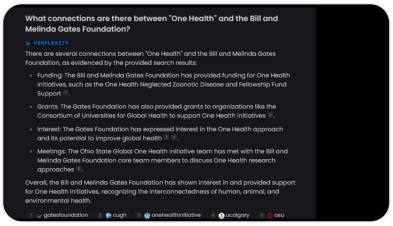


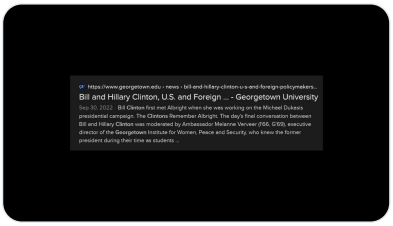


23🧵 The same UC Davis that top EHA member, Jonna Maetz is a member and alumni of. The same One Health program sponsored by Bill & Melinda Gates's foundation & the Clinton Foundation. Speaking of which...



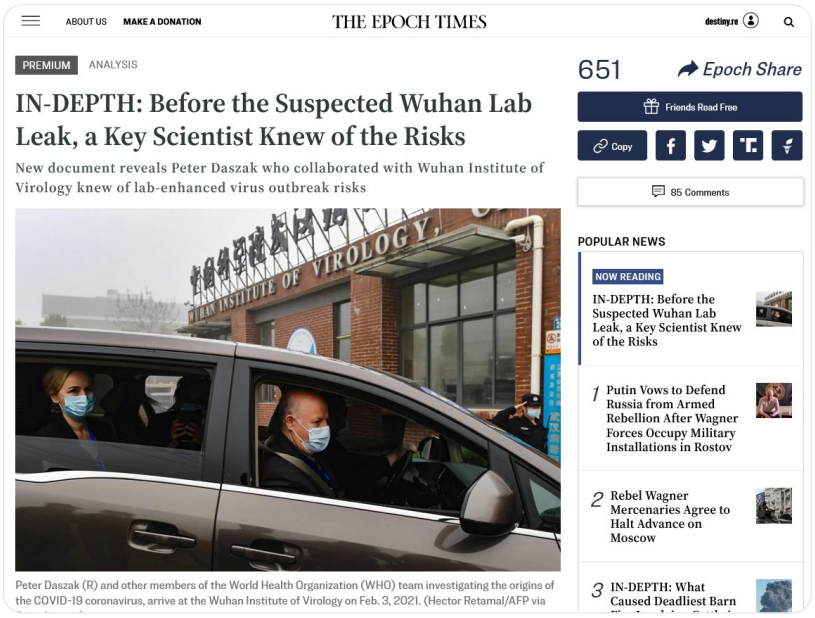






24🧵The Clinton's are long time donors to GU because GU is where President Bill Clinton graduated. (I implore you to look into the web of shady characters that are GU grads btw).

25🧵Other instances of proof that the intelligence community has yet again soiled the American Dream can be found in: @AGHuff admission that while working at EHA, his boss, Daszak had told him his consideration of working with the CIA in 2014.



26🧵It's also seen in the intelligence infested governance of Moderna's C19 vaccine manufacturer Government Resilience Services, aka Resilience ink, amongst its leaders is In-Q-Tel (CIA) president, Chris Darby. Inspired by In-Q-Tel's Luciana Borio

27🧵And also seen in how the intelligence community's recent admission that they knew C19 resulted from a lab leak long ago, yet lacked a public investigation and why people like Daszak have remain unscathed despite millions dead from his work.

28🧵One thing is for certain, history will repeat itself if we, the people, fail to recognize, remember and demand better from our history. We must demand the removal of the CIA from our scientific efforts or remove them fully.

29🧵Don't take my word for it. Research this yourself and then write your government officials, file FOIA's and stay informed. Here's some links- now go give em' hell.

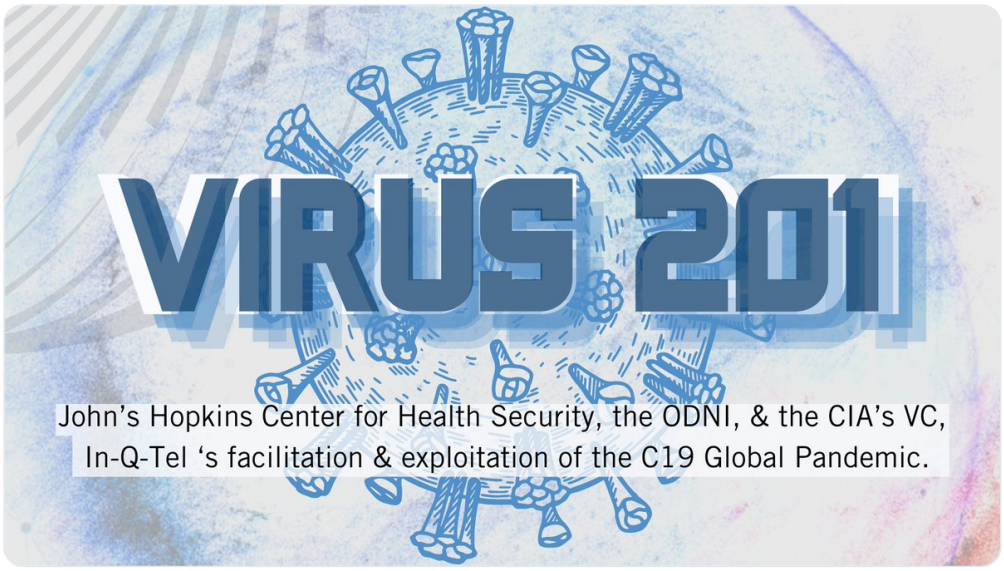
@threadreaderapp unroll this thread

...

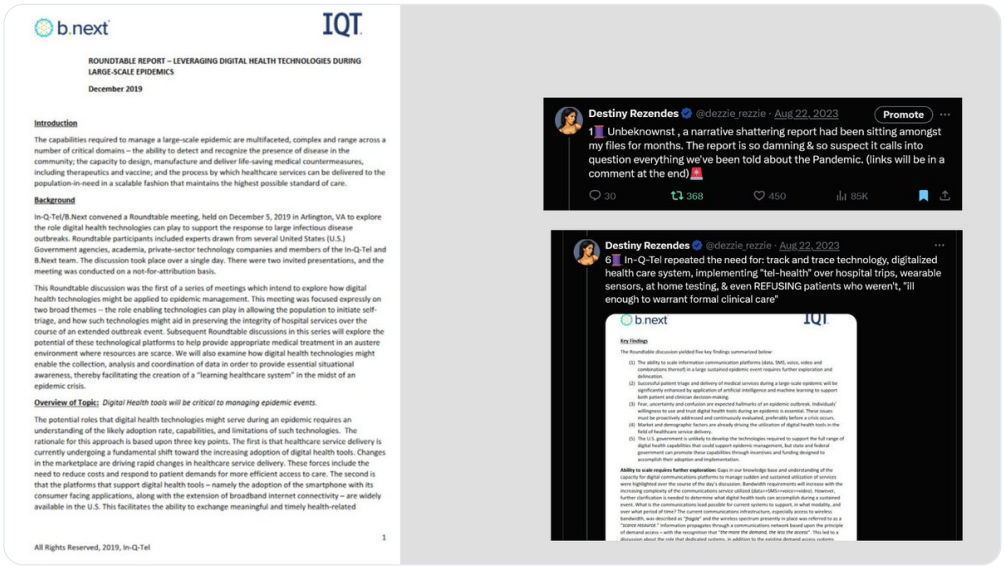
Destiny Rezendes @dezzie_rezzie

Mar 6, 2024 • 19 tweets • dezzie_rezzie/status/1765451927884628134

1🧵 The significant portion of the US Intelligence Community has admitted to believing that the C19 pandemic likely originated in the Wuhan Lab. What they failed to mention is how they strategically facilitated the emergence of C19 & then exploited the response.



2🧵 Seven+ months ago I authored a thread showing the CIA's tech arm, In-Q-Tel [IQT] held a round-table tabletop exercise [TTX] in December of 2019. The TTX foreshadowed a global epidemic that would use machine learning on 5G to manage the "specturm of illness."



3🧵 Now I've found the second In-Q-Tel TTX document that's from November 5, 2019 titled, Delivering the Biorevolution. The document focuses on which vaccine platforms they would like to see in response to an emerging disease pandemic. 2month before C19!

Delivering the biorevolution: a BNext Workshop on cellular delivery technologies

November 5, 2019

Dylan George[1], Tara O'Toole[2], BNext et al

Summary: This workshop was motivated by BNext's interest in technologies that facilitate timely response to infectious disease outbreaks through the rapid design and manufacture of vaccines against newly emergent pathogens.

A compelling technology for rapid response to an ongoing outbreak is nucleic acid-based vaccines. Nucleic acid-based vaccines are attractive for rapid response because, in theory, DNA or RNA antigens that provoke a protective immune response could be quickly and inexpensively designed, manufactured, and used speedily in the clinic. Big pharma and biotech companies are interested in advancing nucleic acid-based vaccines. Several candidates are in clinical trials, though no nucleic acid-based vaccines have achieved FDA approval. Among the hurdles associated with DNA or RNA-based vaccines are the following:

All Available Cellular Delivery Technologies Have Limitations - Major techniques to deliver the nucleic acid "payload" inside cells have been demonstrated - including electroporation, viral vectors and a variety of lipid nanocarriers – but all are problematic. Electroporation is suitable only for laboratory settings and not feasible in a mass casualty setting. Viral vectors carry the risk of unintentional immune reactions, and the virus carrier can only deliver certain types of payloads. Lipid nanocarriers are arguably the most advanced modality and are the delivery vehicle used in seven of eight ongoing RNA vaccine trials and in gene therapy trials. But they too are disadvantaged by the relatively "fragile" supply chain that is being used primarily for other products.

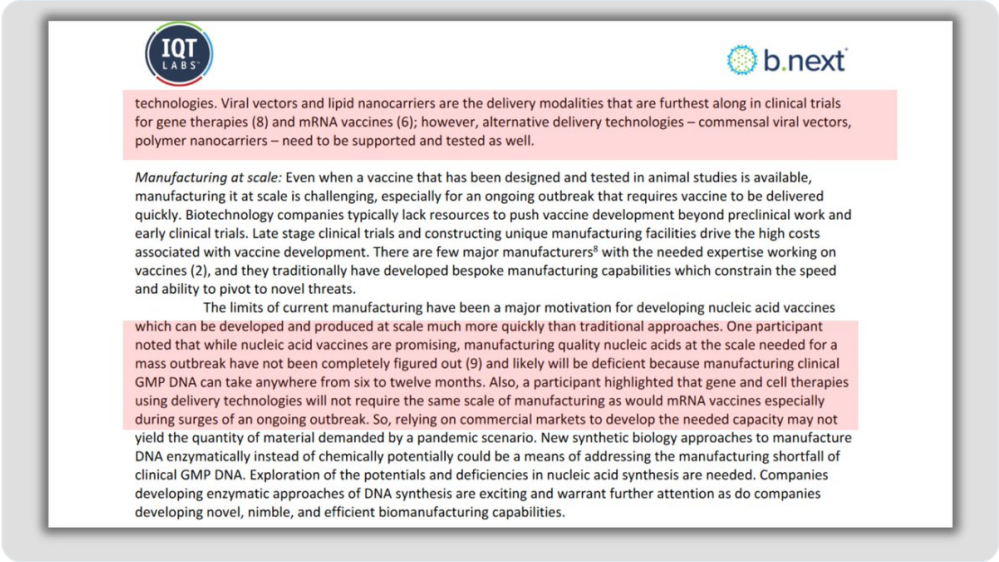
Manufacturing viruses and lipids is itself a hurdle to be overcome, especially if vaccine were needed in large quantities. For example, the supply chain capacity for GMP-grade lipids is limited, and currently being stretched by demand for the second-generation Shingles vaccine.

Similarly, manufacture of GMP-grade nucleic acid at scale is not currently possible at speed and would probably require 12 months. Making DNA in the U.S. Government's Advanced Development Manufacturing Facilities may make this possible in 6 months. Several biotech companies are working hard to improve de novo DNA synthesis, but we are not yet able to do this at the required scale and time frame. DARPA is starting a program to develop novel approaches for DNA manufacturing at scale too.

Regulatory approval of novel cellular delivery methods requires a time-consuming and costly investment of resources, a fact that creates a rational disincentive to innovate. Nonetheless, successful and safe cellular delivery is a central feature of many of the most promising new drugs, including gene therapies. The commercial stakes involved in these new approaches will likely advance the science of cellular delivery, hopefully to the benefit of nucleic acid-based vaccines.

Conclusions: Advances in delivery modalities other than the current mainstays – existing viral vectors, lipid nanocarriers - should be supported. Supporting alternative DNA synthesis technologies and nimble, efficient biomanufacturing capabilities should be a priority.

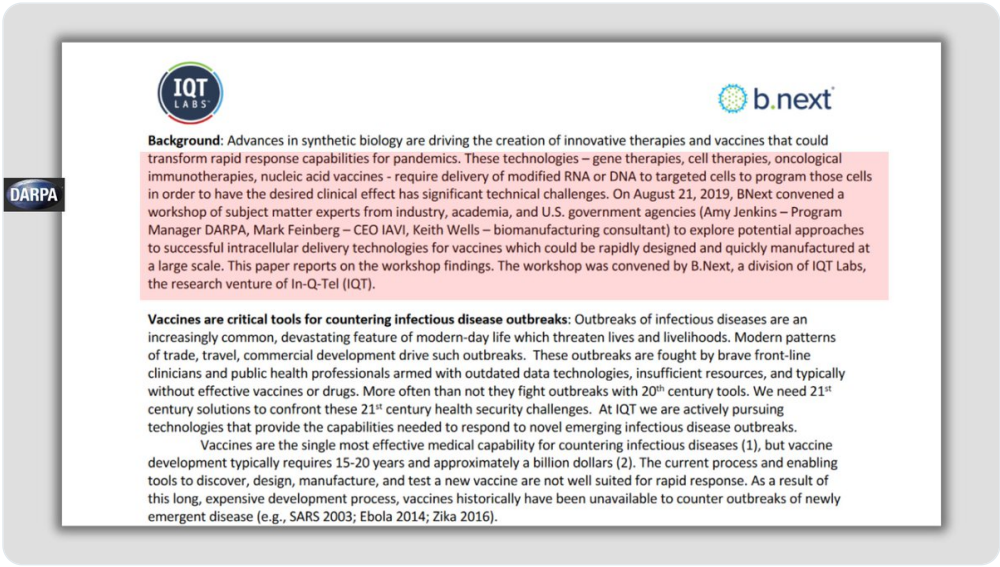
[1] Vice President, BNext, IQT
[2] Executive Vice President, BNext Director, IQT



technologies. Viral vectors and lipid nanocarriers are the delivery modalities that are furthest along in clinical trials for gene therapies (8) and mRNA vaccines (6); however, alternative delivery technologies – commensal viral vectors, polymer nanocarriers – need to be supported and tested as well.

Manufacturing at scale: Even when a vaccine that has been designed and tested in animal studies is available, manufacturing it at scale is challenging, especially for an ongoing outbreak that requires vaccine to be delivered quickly. Biotechnology companies typically lack resources to push vaccine development beyond preclinical work and early clinical trials. Late stage clinical trials and constructing unique manufacturing facilities drive the high costs associated with vaccine development. There are few major manufacturers[8] with the needed expertise working on vaccines (2), and they traditionally have developed bespoke manufacturing capabilities which constrain the speed and ability to pivot to novel threats.

The limits of current manufacturing have been a major motivation for developing nucleic acid vaccines which can be developed and produced at scale much more quickly than traditional approaches. One participant noted that while nucleic acid vaccines are promising, manufacturing quality nucleic acids at the scale needed for a mass outbreak have not been completely figured out (9) and likely will be deficient because manufacturing clinical GMP DNA can take anywhere from six to twelve months. Also, a participant highlighted that gene and cell therapies using delivery technologies will not require the same scale of manufacturing as would mRNA vaccines especially during surges of an ongoing outbreak. So, relying on commercial markets to develop the needed capacity may not yield the quantity of material demanded by a pandemic scenario. New synthetic biology approaches to manufacture DNA enzymatically instead of chemically potentially could be a means of addressing the manufacturing shortfall of clinical GMP DNA. Exploration of the potentials and deficiencies in nucleic acid synthesis are needed. Companies developing enzymatic approaches of DNA synthesis are exciting and warrant further attention as do companies developing novel, nimble, and efficient biomanufacturing capabilities.



Background: Advances in synthetic biology are driving the creation of innovative therapies and vaccines that could transform rapid response capabilities for pandemics. These technologies – gene therapies, cell therapies, oncological immunotherapies, nucleic acid vaccines - require delivery of modified RNA or DNA to targeted cells to program those cells in order to have the desired clinical effect has significant technical challenges. On August 21, 2019, BNext convened a workshop of subject matter experts from industry, academia, and U.S. government agencies (Amy Jenkins – Program Manager DARPA, Mark Feinberg – CEO IAVI, Keith Wells – biomanufacturing consultant) to explore potential approaches to successful intracellular delivery technologies for vaccines which could be rapidly designed and quickly manufactured at a large scale. This paper reports on the workshop findings. The workshop was convened by B.Next, a division of IQT Labs, the research venture of In-Q-Tel (IQT).

Vaccines are critical tools for countering infectious disease outbreaks: Outbreaks of infectious diseases are an increasingly common, devastating feature of modern-day life which threaten lives and livelihoods. Modern patterns of trade, travel, commercial development drive such outbreaks. These outbreaks are fought by brave front-line clinicians and public health professionals armed with outdated data technologies, insufficient resources, and typically without effective vaccines or drugs. More often than not they fight outbreaks with 20th century tools. We need 21st century solutions to confront these 21st century health security challenges. At IQT we are actively pursuing technologies that provide the capabilities needed to respond to novel emerging infectious disease outbreaks.

Vaccines are the single most effective medical capability for countering infectious diseases (1), but vaccine development typically requires 15-20 years and approximately a billion dollars (2). The current process and enabling tools to discover, design, manufacture, and test a new vaccine are not well suited for rapid response. As a result of this long, expensive development process, vaccines historically have been unavailable to counter outbreaks of newly emergent disease (e.g., SARS 2003; Ebola 2014; Zika 2016).

4🧵 Of viral vectors, lipid nanocarriers, GMP DNA, & mRNA the one most praised was mRNA. Reasoning for this was, "RNA-based vaccines can be manufactured cell-free, which reduces complications associated with maintaining GMP cell lines..."

One workshop participant told the group about how the lack of a deployable vaccine allowed the Ebola outbreak of 2014-2016 in West Africa to rampage across Sierra Leone, Liberia and Guinea killing over 11,000 people and significantly destabilizing the region. At the time, no licensed vaccine or therapeutic was available, but several candidate Ebola vaccines had already gone through years of early stage development. Merck Vaccines was willing and able to step into the breach to advance a candidate through later stage development. With support from the USG and others, Merck, at considerable expense, licensed a candidate vaccine, contracted manufacturing capabilities, and began the process of testing the vaccine in hopes of providing life-saving vaccines to people in the region. Merck was able to shorten the development timeline from years to months. Fortunately the outbreak ended before this vaccine could be manufactured and deployed at scale. So, in the end, the vaccine did not significantly contribute to stopping that specific outbreak.

Despite the example of Merck Vaccines and other initiatives[3], participants agreed that we continue to battle novel pathogen outbreaks without effective vaccines (3). Because time is critical during an outbreak, current methods of developing vaccines are not sufficient and technologies that can be designed and manufactured quickly will have more impact. Technologies that enable the discovery, manufacture, development, and use of vaccines in timeframes that would significantly counter an ongoing outbreak remain critically important. Promoting and developing vaccine technologies that enable rapid design and scaled-up manufacture has been a focus of some DARPA programs (e.g., Adept, P3). B.Next also continues to seek technologies that would enable vaccine design and manufacture in timeframes that would be applicable to stopping an epidemic.

Nucleic acid-based vaccines are promising technologies: Nucleic acid vaccines, which deliver DNA or mRNA to generate an antigen, are particularly promising vaccine technologies for rapid outbreak response because, at least in principle, they can be rapidly developed and inexpensively manufactured (4).

mRNA is the intermediate molecule that enables the expression of a gene into a protein. It is the molecule that tells a cell what proteins to build. The idea behind mRNA vaccines is to design and use an mRNA that would tell the body's cells to generate a particular type of protein, an antigen, that will elicit a protective immune response for a specific disease (Figure 1). In short, nucleic acid vaccines biologically "program" a person at the cellular level to generate immunological protection. This programming should work as long as you are able to deliver the right information, that is the right mRNA, to the right cells in a body.

[3] See efforts by the Coalition for Epidemic Preparedness Innovation, https://cepi.net/

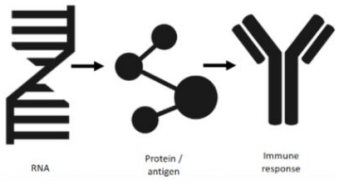


Figure 1. mRNA vaccines program cells to generate immune responses. mRNA vaccines accomplish immune responses by inserting an RNA molecule into cells to program the cellular production of a protective response in the body. The RNA molecule once in the cell is translated to a protein molecule. The protein, or rather antigen, elicits an immune response – generates antibodies or other mechanisms - that provides protection from the pathogen.

An advantage to mRNA vaccines is that RNA can be designed and, in theory, synthesized quickly using standardized processes. Traditional vaccine manufacturing is bespoke and typically requires a unique and expensive manufacturing facility for each vaccine, whereas with RNA production one manufacturing facility could be used for multiple vaccines because you are using a standardized system for RNA synthesis. Also, RNA-based vaccines can be manufactured cell-free, which reduces complications associated with maintaining GMP cell lines (5). Development of a mRNA vaccine can go from genetic sequence to mass production in three months, whereas traditional approaches would take many months to years to produce a new vaccine at scale. Despite such promise, however, no nucleic acid vaccines have yet been approved by the FDA, although several candidate vaccines have progressed to phase 1, 2 clinical trials (6).

Several participants were cautiously hopeful that mRNA vaccines could provide capabilities to address the challenges of rapid vaccine development, but the clinical trials still need to demonstrate candidate mRNA vaccines are safe and

Intracellular delivery: a vital component for effective vaccines: A major challenge with nucleic acid vaccines is getting the genetic payload to the right place in the body so one's immune system can generate protection. The safe and effective delivery of genetic payloads within humans has been a focus for decades (7), (8).

Intracellular delivery includes not just the process of getting materials through cellular membranes, but also entails protecting payloads from degradation processes, and releasing payloads into a cell in a reliable way (3). Intracellular delivery is a linchpin for a range of therapeutic applications beyond vaccines, including gene-editing technologies. Participants noted that several Phase I trials of nucleic acid vaccines nusing novel delivery technologies are underway (4), (8), (9).

Participants discussed the three main delivery modalities for vaccines: electroporation, viral vectors, and lipid nanocarriers.

Electroporation is the process of applying an electrical field to a cell such that cellular membranes become transiently permeable, molecular cargo moves across the membrane, the cargo can be inserted into the cell, and the membrane is resealed (Figure 2). Electroporation has been used in microbiology since the 1970s and is widely used in basic and biomedical research. But there are limitations to its use outside a lab or in a mass administration situation. The process can be highly efficient, but it is expensive and can create cell death if the electrical fields cause a permanent destabilization of a cell membrane or components. Electroporation can cause pain and muscle contractions which makes it less than appealing for treatment adherence if more than one dose is required. Most importantly, electroporation requires equipment to establish the electrical field and the portability of this equipment limits how widely it could be used outside of a clinic or laboratory setting. The value of electroporation is most apparent for *in vitro* and *ex vivo* investigations and applications, and not necessarily *in vivo* delivery.

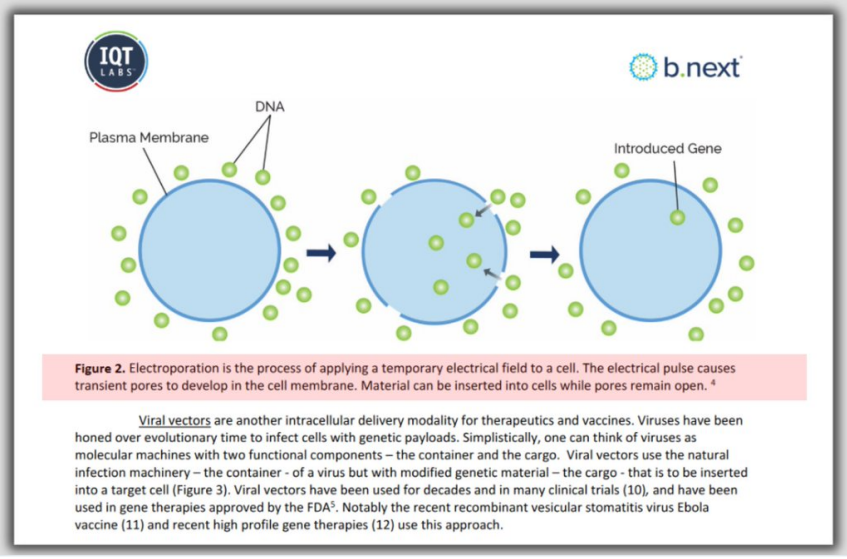


Figure 2. Electroporation is the process of applying a temporary electrical field to a cell. The electrical pulse causes transient pores to develop in the cell membrane. Material can be inserted into cells while pores remain open. [4]

Viral vectors are another intracellular delivery modality for therapeutics and vaccines. Viruses have been honed over evolutionary time to infect cells with genetic payloads. Simplistically, one can think of viruses as molecular machines with two functional components – the container and the cargo. Viral vectors use the natural infection machinery – the container - of a virus but with modified genetic material – the cargo - that is to be inserted into a target cell (Figure 3). Viral vectors have been used for decades and in many clinical trials (10), and have been used in gene therapies approved by the FDA[5]. Notably the recent recombinant vesicular stomatitis virus Ebola vaccine (11) and recent high profile gene therapies (12) use this approach.

5 🧵 "Development of a mRNA vaccine can go from genetic sequence to mass production in three months, whereas traditional approaches would take many months to years to produce a new vaccine at scale."

⚠️Their top concern was ease & speed-not effectiveness or safety.👿

immune responses to particular viral vectors. If this happens then the continued use of those vectors will not be possible in those individuals which will limit the therapeutics and vaccines that are in those vectors. Viral vectors are also limited by challenges in manufacturing large quantities of virus, the size of payloads, and by their ability to target many cell types. If the viral vector cannot infect certain types of cells, then we will not be able to program those cells with the genetic payloads. Finding viral vectors that can target specific cells will be an ongoing effort. So, researchers are actively searching for alternative viral vector systems to counter these limitations[6].

Lipid Nanocarriers - Delivering nucleic acids or proteins cargo into cells can be achieved by using chemical reagents to construct delivery vehicles that have different properties. Many alternative cell delivery approaches such as lipid nanocarriers, polymer nanocarriers, and other nanomaterials have been explored to bypass the limitations of viral vectors (13). Lipid nanocarriers are the most advanced of these technologies for nucleic acid delivery (8), are currently being used in the majority of current clinical trials on mRNA vaccines (6), and were used in the first RNAi drug ("Patisiran"), approved by the FDA in August 2018. A recent review of mRNA clinical trials and delivery modalities found that seven of the eight of the ongoing clinical trials on mRNA vaccines are using lipid nanoparticles as their intracellular delivery modality (6).

Carrier systems based on chemical reagents can be limited by the features of the cargo (e.g., size, chemical properties, unpackaging abilities) and the target cell types. As with viral vectors, getting into some cell types is easier than others depending on cell receptors, surface interactions, and internal cellular processing pathways. For example, immortalized cell lines can be easily transfected, whereas blood and neurological cells pose difficulties (8). Because lipid nanocarriers have been easier to make relative to viral vectors, generate adjuvant effects, and do not generate unintended immunogenic responses, they have been broadly used to deliver nucleic acids in drug development. But see below for the challenges associated with "fragile" supply chains associated with lipid nanocarriers.

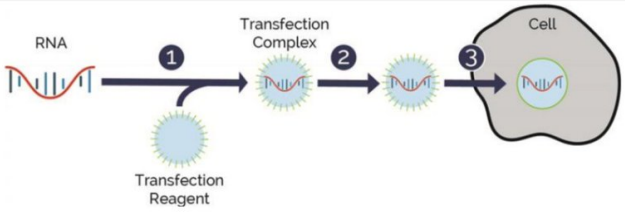
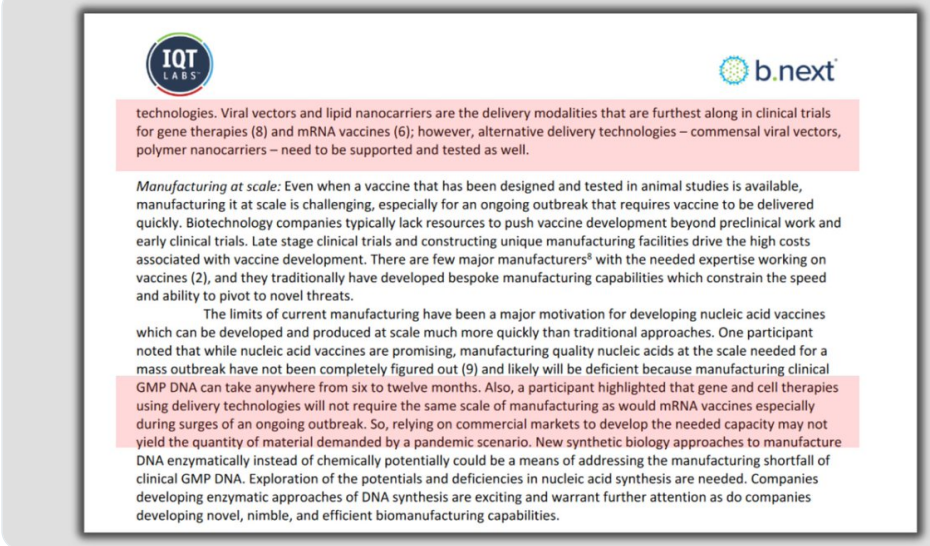


Figure 4: Getting programmed RNA into cells – the transfection process: 1) A chemical reagent is combined with a nucleic acid making a chemical complex of the two entities. **2)** The combined reagent and nucleic acid interact with the cell surface. **3)** Cells internalize the complex and the nucleic acid is ultimately released to the cell cytoplasm. [7]

Challenges and opportunities:

Regulatory: A major regulatory issue is the innovation disincentive within big pharma. An effective regulatory environment for medical countermeasures is necessary but can slow innovation. For biological pharmaceuticals such as vaccines, the manufacturing process itself contains much of the valuable intellectual property. To meet regulatory standards, the production process must reliably produce the same product which requires considerable investment of time and resources. Once a process has been validated and approved by a regulatory agency there is a rational disincentive to modify the process because major changes would require further regulatory approval and cost to provide the needed data. (14). Regulatory disincentives slow the pace of innovation for intracellular delivery

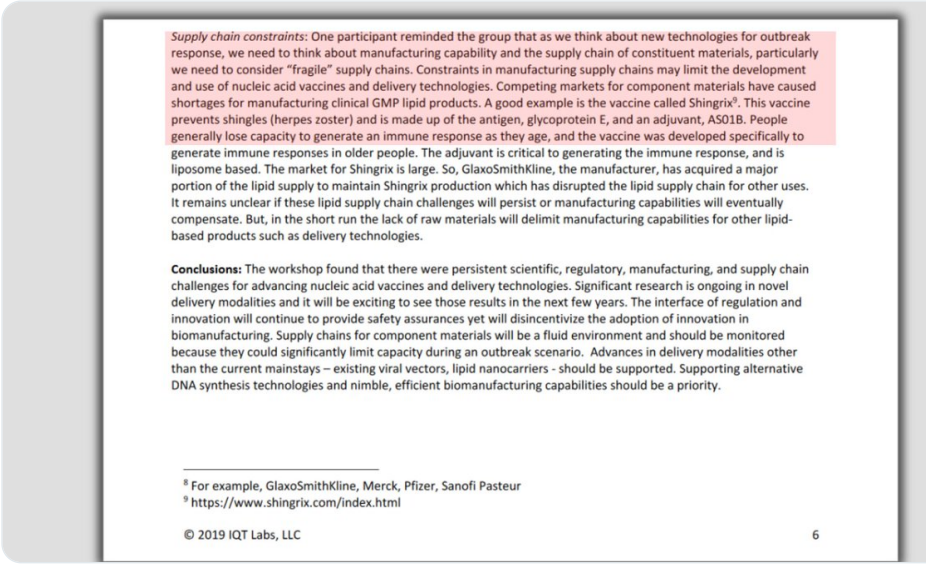
[6] For example, see the company Ring Therapeutics.
[7] Based on figure from https://www.mirusbio.com.



technologies. Viral vectors and lipid nanocarriers are the delivery modalities that are furthest along in clinical trials for gene therapies (8) and mRNA vaccines (6); however, alternative delivery technologies – commensal viral vectors, polymer nanocarriers – need to be supported and tested as well.

Manufacturing at scale: Even when a vaccine that has been designed and tested in animal studies is available, manufacturing it at scale is challenging, especially for an ongoing outbreak that requires vaccine to be delivered quickly. Biotechnology companies typically lack resources to push vaccine development beyond preclinical work and early clinical trials. Late stage clinical trials and constructing unique manufacturing facilities drive the high costs associated with vaccine development. There are few major manufacturers[8] with the needed expertise working on vaccines (2), and they traditionally have developed bespoke manufacturing capabilities which constrain the speed and ability to pivot to novel threats.

The limits of current manufacturing have been a major motivation for developing nucleic acid vaccines which can be developed and produced at scale much more quickly than traditional approaches. One participant noted that while nucleic acid vaccines are promising, manufacturing quality nucleic acids at the scale needed for a mass outbreak have not been completely figured out (9) and likely will be deficient because manufacturing clinical GMP DNA can take anywhere from six to twelve months. Also, a participant highlighted that gene and cell therapies using delivery technologies will not require the same scale of manufacturing as would mRNA vaccines especially during surges of an ongoing outbreak. So, relying on commercial markets to develop the needed capacity may not yield the quantity of material demanded by a pandemic scenario. New synthetic biology approaches to manufacture DNA enzymatically instead of chemically potentially could be a means of addressing the manufacturing shortfall of clinical GMP DNA. Exploration of the potentials and deficiencies in nucleic acid synthesis are needed. Companies developing enzymatic approaches of DNA synthesis are exciting and warrant further attention as do companies developing novel, nimble, and efficient biomanufacturing capabilities.



Supply chain constraints: One participant reminded the group that as we think about new technologies for outbreak response, we need to think about manufacturing capability and the supply chain of constituent materials, particularly we need to consider "fragile" supply chains. Constraints in manufacturing supply chains may limit the development and use of nucleic acid vaccines and delivery technologies. Competing markets for component materials have caused shortages for manufacturing clinical GMP lipid products. A good example is the vaccine called Shingrix[9]. This vaccine prevents shingles (herpes zoster) and is made up of the antigen, glycoprotein E, and an adjuvant, AS01B. People generally lose capacity to generate an immune response as they age, and the vaccine was developed specifically to generate immune responses in older people. The adjuvant is critical to generating the immune response, and is liposome based. The market for Shingrix is large. So, GlaxoSmithKline, the manufacturer, has acquired a major portion of the lipid supply to maintain Shingrix production which has disrupted the lipid supply chain for other uses. It remains unclear if these lipid supply chain challenges will persist or manufacturing capabilities will eventually compensate. But, in the short run the lack of raw materials will delimit manufacturing capabilities for other lipid-based products such as delivery technologies.

Conclusions: The workshop found that there were persistent scientific, regulatory, manufacturing, and supply chain challenges for advancing nucleic acid vaccines and delivery technologies. Significant research is ongoing in novel delivery modalities and it will be exciting to see those results in the next few years. The interface of regulation and innovation will continue to provide safety assurances yet will disincentivize the adoption of innovation in biomanufacturing. Supply chains for component materials will be a fluid environment and should be monitored because they could significantly limit capacity during an outbreak scenario. Advances in delivery modalities other than the current mainstays – existing viral vectors, lipid nanocarriers - should be supported. Supporting alternative DNA synthesis technologies and nimble, efficient biomanufacturing capabilities should be a priority.

[8] For example, GlaxoSmithKline, Merck, Pfizer, Sanofi Pasteur
[9] https://www.shingrix.com/index.html

6 An author of the TTX was Tara O'Toole who not only is VP at IQT, & laboratories, but she is also the DoDs premier doomsday TTX writers and a senior advisor for Johns Hopkins Center for Health Security [JHCHS] B.Next

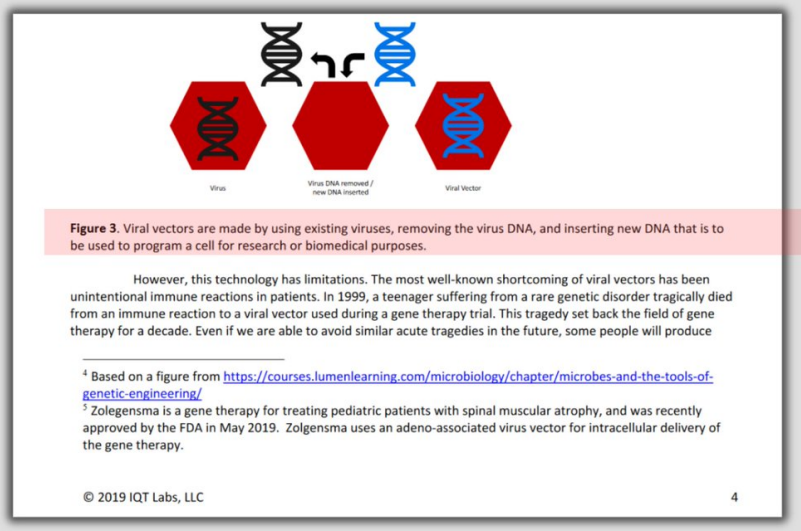
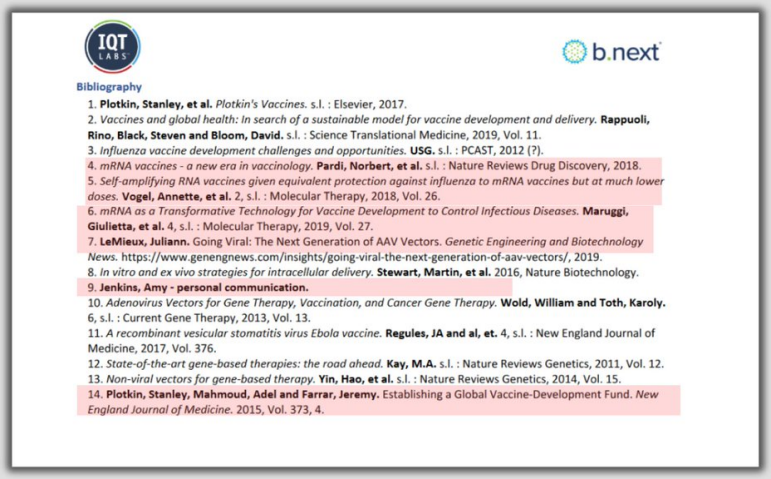


Figure 3. Viral vectors are made by using existing viruses, removing the virus DNA, and inserting new DNA that is to be used to program a cell for research or biomedical purposes.

However, this technology has limitations. The most well-known shortcoming of viral vectors has been unintentional immune reactions in patients. In 1999, a teenager suffering from a rare genetic disorder tragically died from an immune reaction to a viral vector used during a gene therapy trial. This tragedy set back the field of gene therapy for a decade. Even if we are able to avoid similar acute tragedies in the future, some people will produce

[4] Based on a figure from https://courses.lumenlearning.com/microbiology/chapter/microbes-and-the-tools-of-genetic-engineering/

[5] Zolegensma is a gene therapy for treating pediatric patients with spinal muscular atrophy, and was recently approved by the FDA in May 2019. Zolgensma uses an adeno-associated virus vector for intracellular delivery of the gene therapy.



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7🧵 As a re-cap on the first IQT TTX which was 1 month before the pandemic and among its listed authors were: CDC, DOD, ASPR, Luciano Borio[IQT/FDA], O'Toole, Robert Walker [ARMY] & Event 201s Top script writer/senior analyst Eric Toner of JHCHS.

Participant List:

Dr. Rima Abdel-Massih	ID Connect, University of Pittsburgh Medical Center Enterprises
Mr. J.J. Ben-Joseph	IQT/B.Next, Technical Staff
Dr. Luciana Borio	IQT/B.Next, Technical Staff
Mr. Joseph Buccina	IQT/B.Next, Director of IC Support and B.Next Operations
Dr. Brendan Carr	Director, Emergency Care Coordination Center, HHS/ASPR
Mr. Eugene Chiu	IQT/B.Next, Investment Team Member
Mr. Julius Dodson	IQT/B.Next, Intern
Dr. Dylan George	IQT/B.Next, Technical Staff
Dr. M. Kathleen Glynn	Deputy Director, Center for Preparedness and Response, CDC
Dr. Dan Hanfling	IQT/B.Next, Technical Staff
Dr. Andrew Le	CEO, Buoy Health
Mr. Eric Mair	IQT, Technical Staff
Dr. Carrie McNeil (phone)	Sandia National Laboratories, Technical Staff
Mr. Michael Meyer	CEO, Quiq
Mr. W.B. "Mitch" Mitchell	Group Vice President, Government Solutions, American Well
Mr. Isaac Myaou	IQT, Technical Staff
Dr. Kevin O'Connell	IQT, Technical Staff
Dr. Tara O'Toole	IQT/B.Next, Executive Vice President
Dr. Anita Patel (phone)	Senior Advisor, Influenza Coordination Unit, CDC
Dr. Stephanie Rogers	IQT/B.Next, VP, Lab Operations and Bioinformatics
Mr. Ran Shaul	Co-founder, KHealth
Dr. Eric Toner	Senior Scholar, Johns Hopkins Center for Health Security
Mr. James Tyson	Branch Chief, Situational Awareness Office, CDC
Dr. Robert Walker	Office of the Army Surgeon General
Mr. Grant Whiting (phone)	IQT/B.Next, Investment Team Member
Dr. David Whittaker	CMO, DHA Innovation Group, Office of the Secretary of Defense

b.next IQT

ROUNDTABLE REPORT – LEVERAGING DIGITAL HEALTH TECHNOLOGIES DURING LARGE-SCALE EPIDEMICS

December 2019

Introduction

The capabilities required to manage a large-scale epidemic are multifaceted, complex and range across a number of critical domains – the ability to detect and recognize the presence of disease in the community; the capacity to design, manufacture and deliver life-saving medical countermeasures, including therapeutics and vaccine; and the process by which healthcare services can be delivered to the population-in-need in a scalable fashion that maintains the highest possible standard of care.

Background

In-Q-Tel/B.Next convened a Roundtable meeting, held on December 5, 2019 in Arlington, VA to explore the role digital health technologies can play to support the response to large infectious disease outbreaks. Roundtable participants included experts drawn from several United States (U.S.) Government agencies, academia, private-sector technology companies and members of the In-Q-Tel and B.Next team. The discussion took place over a single day. There were two invited presentations, and the meeting was conducted on a not-for-attribution basis.

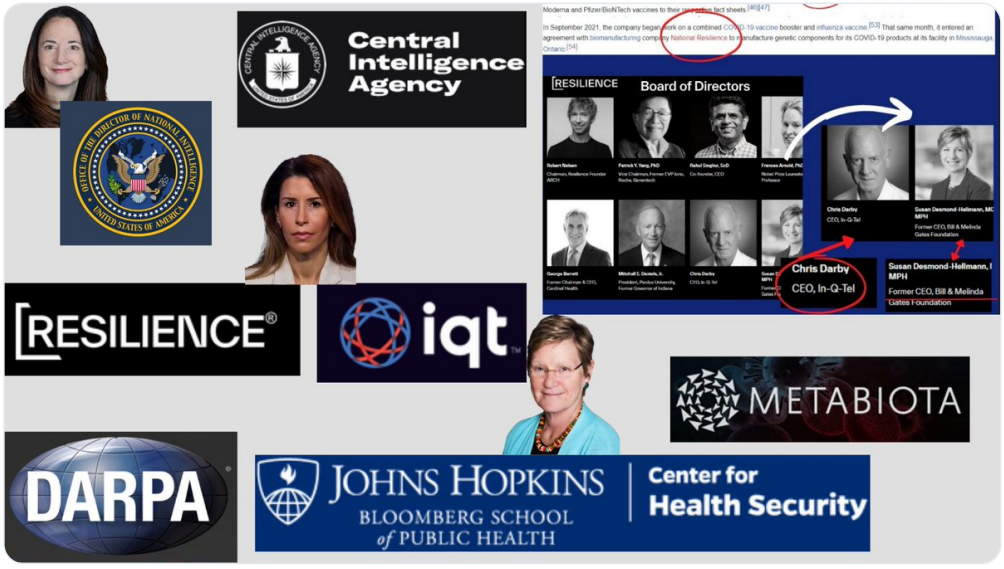
This Roundtable discussion was the first of a series of meetings which intend to explore how digital health technologies might be applied to epidemic management. This meeting was focused expressly on two broad themes -- the role enabling technologies can play in allowing the population to initiate self-triage, and how such technologies might aid in preserving the integrity of hospital services over the course of an extended outbreak event. Subsequent Roundtable discussions in this series will explore the potential of these technological platforms to help provide appropriate medical treatment in an austere environment where resources are scarce. We will also examine how digital health technologies might enable the collection, analysis and coordination of data in order to provide essential situational awareness, thereby facilitating the creation of a "learning healthcare system" in the midst of an epidemic crisis.

Overview of Topic: *Digital Health tools will be critical to managing epidemic events.*

The potential roles that digital health technologies might serve during an epidemic requires an understanding of the likely adoption rate, capabilities, and limitations of such technologies. The rationale for this approach is based upon three key points. The first is that healthcare service delivery is currently undergoing a fundamental shift toward the increasing adoption of digital health tools. Changes in the marketplace are driving rapid changes in healthcare service delivery. These forces include the need to reduce costs and respond to patient demands for more efficient access to care. The second is that the platforms that support digital health tools – namely the adoption of the smartphone with its consumer facing applications, along with the extension of broadband internet connectivity – are widely available in the U.S. This facilitates the ability to exchange meaningful and timely health-related

1

8🧵Where this all become extremely concerning is within the context. The CIAs In-Q-Tel massively funded Palantir & Metabiota additionally the President of IQT, Chris Darby sits on the Board for the C19💉maker for Moderna, National Resilience.



Luciana Borio: Former FDA Chief Scientist, VP of the CIA's In-Q-Tel, CFR, COVAX, President's Transition COVID-19 Advisory Board, Arch Ventures, Inspired the creation of Moderna's C19 Manufacturer, National Resilience Inc, Johns Hopkins Alumni & Advisor, Partner w. BMGF

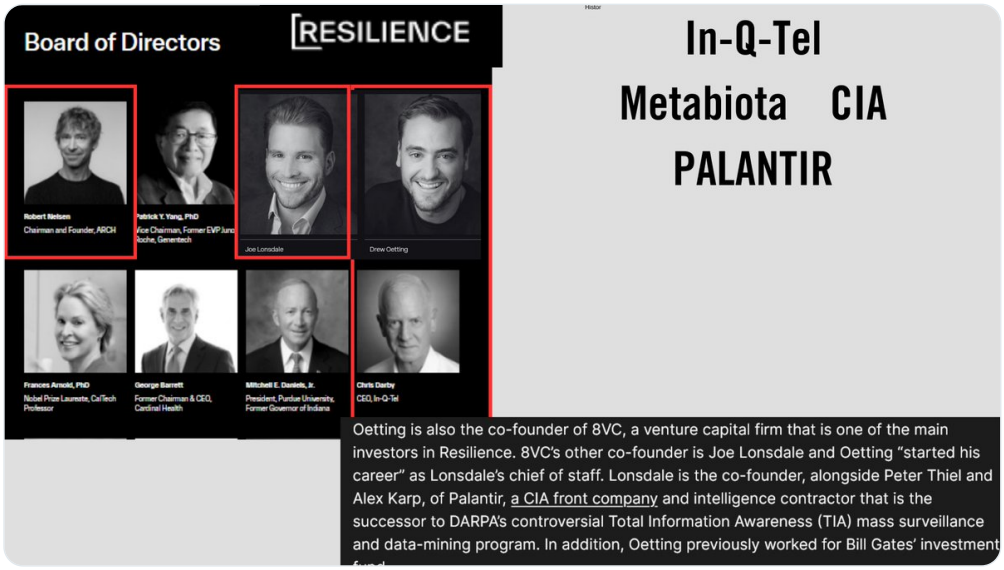
Robert Nelson: Founder & Board of Directors for National Resilience [Moderna's C19 manufacturer], Founder of Arch Ventures, CFR

Chris Darby: Board of Directors for National Resilience [Moderna's C19 manufacturer], President of the CIA's In-Q-Tel.

Tara O'Toole: Senior Advisor at Johns Hopkins Center For Health Security [JHCHS], Pandemic exercise author: Crimson Contagion, Dark Winter, B.Next Lab, VP In-Q-Tel, Under Sec of Homeland Security for Science & Tech under Obama.

Avril Haines: Former CIA Director under Obama, Managing Director for President Biden's Transition Team, Event 201 Player, Johns Hopkins University Drop-out, current director for the ODNI, Georgetown Alum.

9🧵 To make matters worse, Resilience was founded by Robert Nelson[Board of Directors for Resilience] who credited Luciana Borio for inspiring the company's creation. Also Joe Lonsdale of Resilience co-founded Palantir which managed Operation Warp Speed [OWS] w/the DoD for C19.



10🧵Now, remember that O'toole, Toner, & Borio are all JHCHS, which is who hosted Event 201. At Event 201 our current head of the ODNI & FORMER CIA DIRECTOR, Avril Haines [Johns Hopkins drop out] was an official player at the event & ODNI lead the investigation into the origins of the pandemic!

11🧵The JHCHS team were very busy because they had also done a paper for the Global Preparedness Monitoring Board [GPMB] Sept of 2019; predicting a respiratory pandemic-that might have been leaked from a lab. On the GPMB board for the paper? Dr. Anthony Fauci.⚠️

World Health Organization + WORLD BANK GROUP

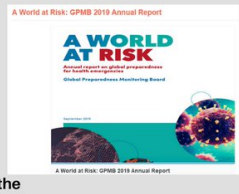
GPMB

The WHO + The World Bank created the Global Preparedness Monitoring Board in 2017

In September of 2019, the GPMB commissioned a white paper with JHCHS titled "Preparedness for a High Impact Respiratory Pandemic"

The writers of this document also wrote the script for Event 201, less than one month later.

Founding Board Member for GPMB at the time of the paper's commissioning was NIAID Director Anthony Fauci.



This report was commissioned by and prepared for the Global Preparedness Monitoring Board.

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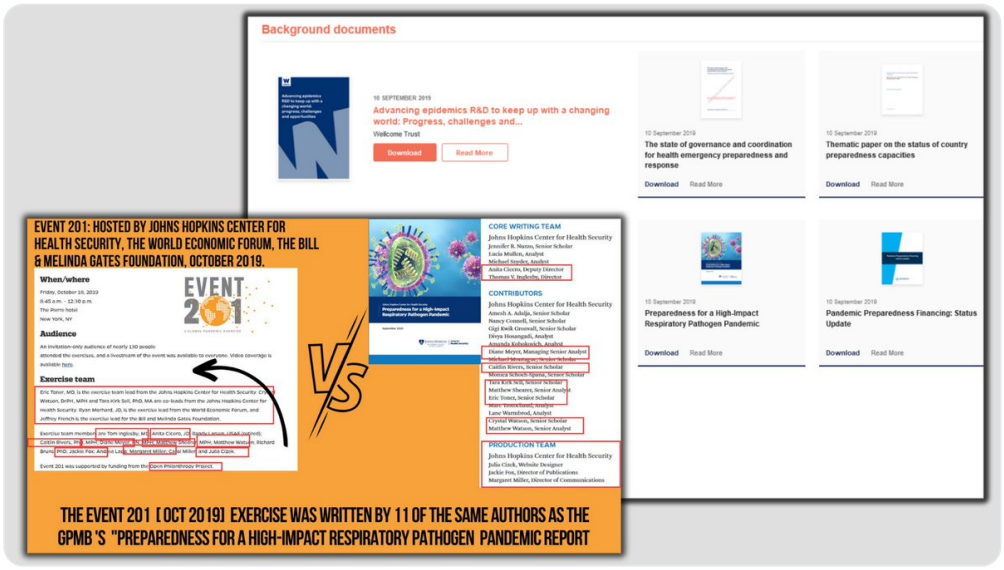
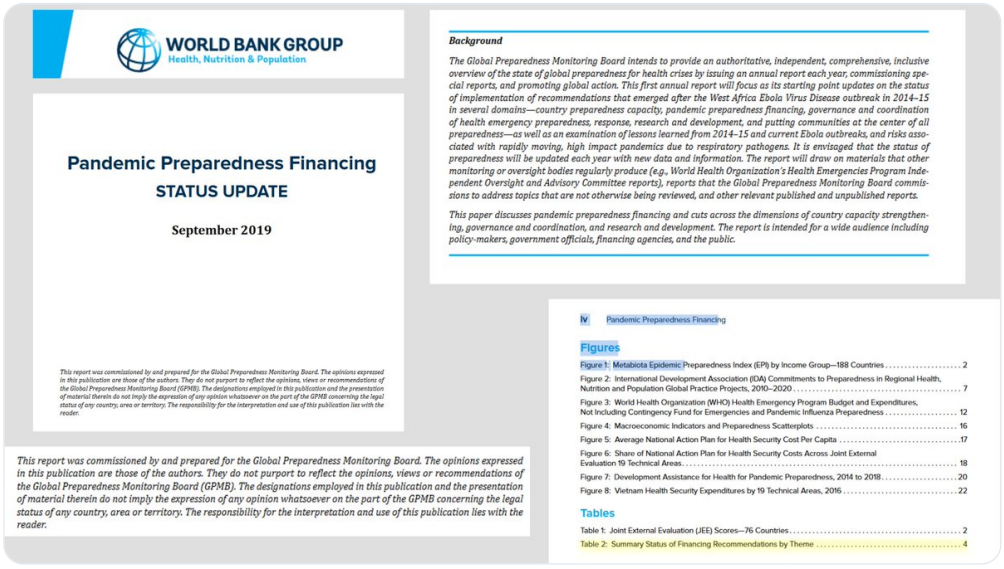
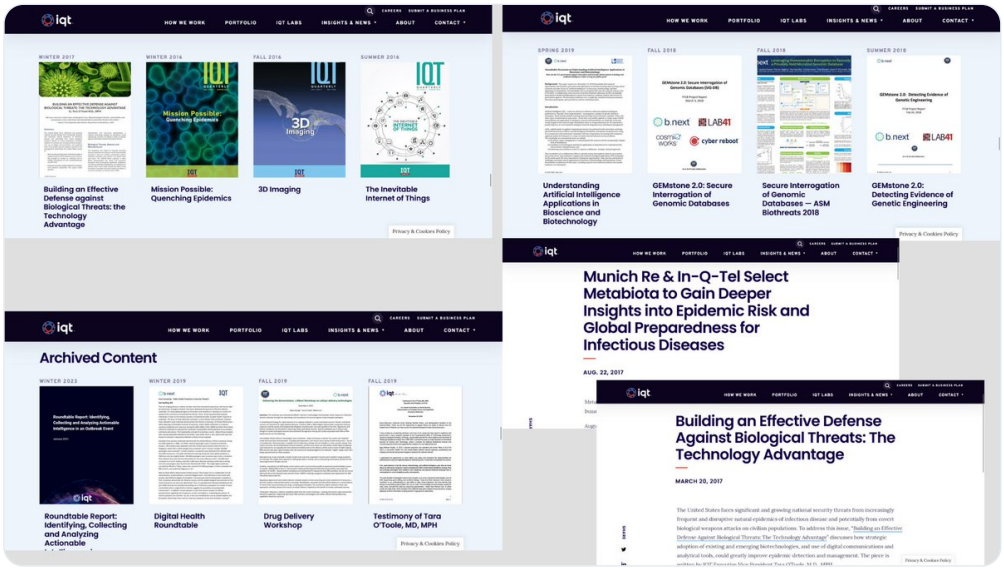
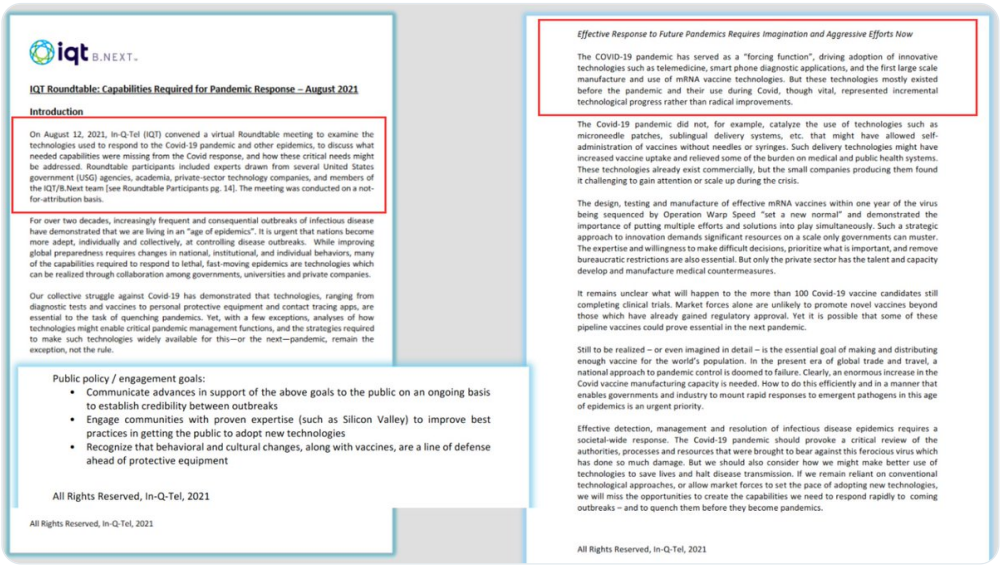


12🧵 And who created the GPMB [est 2017] The WHO & the World Bank. In September of 2019 the World Bank + GPMB [Fauci] released "PANDEMIC PREPAREDNESS FINANCING STATUS UPDATE" & to whom did they employ for their index data? Metabiota.





13🧵 Fast forward to post C19 emergence & we find that IQT released a 3rd round-table in 2021. In it they say, "The C19 pandemic has served as a “forcing function” & that "The design, testing & manufacture of effective mRNA vaccines w/in 1yr of the virus being sequenced by Operation Warp Speed “set a new normal.”



iqt B.NEXT

IQT Roundtable: Capabilities Required for Pandemic Response – August 2021

Introduction

On August 12, 2021, In-Q-Tel (IQT) convened a virtual Roundtable meeting to examine the technologies used to respond to the Covid-19 pandemic and other epidemics, to discuss what needed capabilities were missing from the Covid response, and how these critical needs might be addressed. Roundtable participants included experts drawn from several United States government (USG) agencies, academia, private-sector technology companies, and members of the IQT/B.Next team [see Roundtable Participants pg. 14]. The meeting was conducted on a not-for-attribution basis.

For over two decades, increasingly frequent and consequential outbreaks of infectious disease have demonstrated that we are living in an "age of epidemics". It is urgent that nations become more adept, individually and collectively, at controlling disease outbreaks. While improving global preparedness requires changes in national, institutional, and individual behaviors, many of the capabilities required to respond to lethal, fast-moving epidemics are technologies which can be realized through collaboration among governments, universities and private companies.

Our collective struggle against Covid-19 has demonstrated that technologies, ranging from diagnostic tests and vaccines to personal protective equipment and contact tracing apps, are essential to the task of quenching pandemics. Yet, with a few exceptions, analyses of how technologies might enable critical pandemic management functions, and the strategies required to make such technologies widely available for this—or the next—pandemic, remain the exception, not the rule.

Public policy / engagement goals:

- Communicate advances in support of the above goals to the public on an ongoing basis to establish credibility between outbreaks
- Engage communities with proven expertise (such as Silicon Valley) to improve best practices in getting the public to adopt new technologies
- Recognize that behavioral and cultural changes, along with vaccines, are a line of defense ahead of protective equipment

Effective Response to Future Pandemics Requires Imagination and Aggressive Efforts Now

The COVID-19 pandemic has served as a "forcing function", driving adoption of innovative technologies such as telemedicine, smart phone diagnostic applications, and the first large scale manufacture and use of mRNA vaccine technologies. But these technologies mostly existed before the pandemic and their use during Covid, though vital, represented incremental technological progress rather than radical improvements.

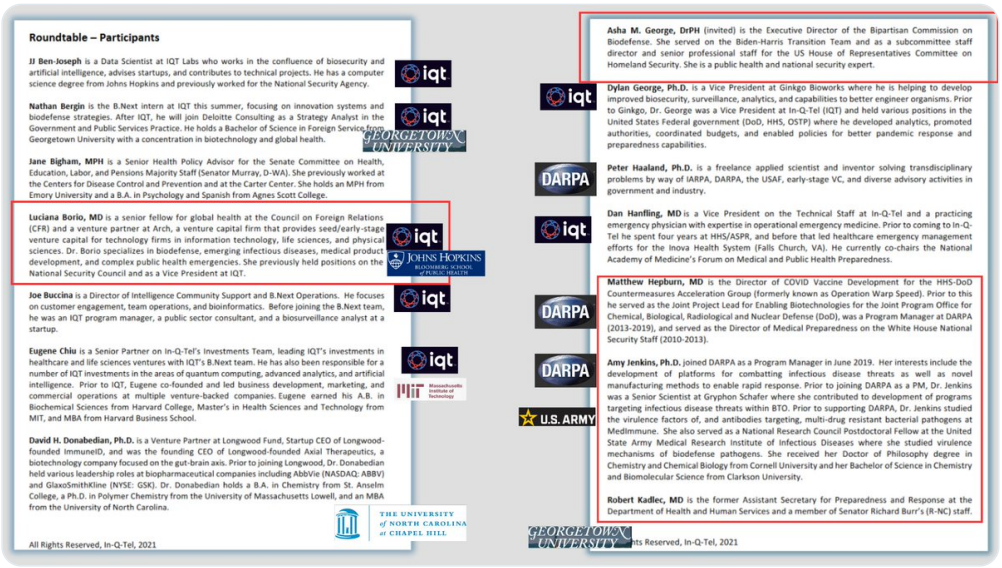
The Covid-19 pandemic did not, for example, catalyze the use of technologies such as microneedle patches, sublingual delivery systems, etc. that might have allowed self-administration of vaccines without needles or syringes. Such delivery technologies might have increased vaccine uptake and relieved some of the burden on medical and public health systems. These technologies already exist commercially, but the small companies producing them found it challenging to gain attention or scale up during the crisis.

The design, testing and manufacture of effective mRNA vaccines within one year of the virus being sequenced by Operation Warp Speed "set a new normal" and demonstrated the importance of putting multiple efforts and solutions into play simultaneously. Such a strategic approach to innovation demands significant resources on a scale only governments can muster. The expertise and willingness to make difficult decisions, prioritize what is important, and remove bureaucratic restrictions are also essential. But only the private sector has the talent and capacity develop and manufacture medical countermeasures.

It remains unclear what will happen to the more than 100 Covid-19 vaccine candidates still completing clinical trials. Market forces alone are unlikely to promote novel vaccines beyond those which have already gained regulatory approval. Yet it is possible that some of these pipeline vaccines could prove essential in the next pandemic.

Still to be realized – or even imagined in detail – is the essential goal of making and distributing enough vaccine for the world's population. In the present era of global trade and travel, a national approach to pandemic control is doomed to failure. Clearly, an enormous increase in the Covid vaccine manufacturing capacity is needed. How to do this efficiently and in a manner that enables governments and industry to mount rapid responses to emergent pathogens in this age of epidemics is an urgent priority.

Effective detection, management and resolution of infectious disease epidemics requires a societal-wide response. The Covid-19 pandemic should provoke a critical review of the authorities, processes and resources that were brought to bear against this ferocious virus which has done so much damage. But we should also consider how we might make better use of technologies to save lives and halt disease transmission. If we remain reliant on conventional technological approaches, or allow market forces to set the pace of adopting new technologies, we will miss the opportunities to create the capabilities we need to respond rapidly to coming outbreaks – and to quench them before they become pandemics.



Roundtable – Participants

JJ Ben-Joseph is a Data Scientist at IQT Labs who works in the confluence of biosecurity and artificial intelligence, advises startups, and contributes to technical projects. He has a computer science degree from Johns Hopkins and previously worked for the National Security Agency.

Nathan Bergin is the B.Next intern at IQT this summer, focusing on innovation systems and biodefense strategies. After IQT, he will join Deloitte Consulting as a Strategy Analyst in the Government and Public Services Practice. He holds a Bachelor of Science in Foreign Service from Georgetown University with a concentration in biotechnology and global health.

Jane Bigham, MPH is a Senior Health Policy Advisor for the Senate Committee on Health, Education, Labor, and Pensions Majority Staff (Senator Murray, D-WA). She previously worked at the Centers for Disease Control and Prevention and at the Carter Center. She holds an MPH from Emory University and a B.A. in Psychology and Spanish from Agnes Scott College.

Luciana Borio, MD is a senior fellow for global health at the Council on Foreign Relations (CFR) and a venture partner at Arch, a venture capital firm that provides seed/early-stage venture capital for technology firms in information technology, life sciences, and physical sciences. Dr. Borio specializes in biodefense, emerging infectious diseases, medical product development, and complex public health emergencies. She previously held positions on the National Security Council and as a Vice President at IQT.

Joe Buccina is a Director of Intelligence Community Support and B.Next Operations. He focuses on customer engagement, team operations, and bioinformatics. Before joining the B.Next team, he was an IQT program manager, a public sector consultant, and a biosurveillance analyst at a startup.

Eugene Chiu is a Senior Partner on In-Q-Tel's Investments Team, leading IQT's investments in healthcare and life sciences ventures with IQT's B.Next team. He has also been responsible for a number of IQT investments in the areas of quantum computing, advanced analytics, and artificial intelligence. Prior to IQT, Eugene co-founded and led business development, marketing, and commercial operations at multiple venture-backed companies. Eugene earned his A.B. in Biochemical Sciences from Harvard College, Master's in Health Sciences and Technology from MIT, and MBA from Harvard Business School.

David H. Donabedian, Ph.D. is a Venture Partner at Longwood Fund, Startup CEO of Longwood-founded ImmuneID, and was the founding CEO of Longwood-founded Axial Therapeutics, a biotechnology company focused on the gut-brain axis. Prior to joining Longwood, Dr. Donabedian held various leadership roles at biopharmaceutical companies including AbbVie (NASDAQ: ABBV) and GlaxoSmithKline (NYSE: GSK). Dr. Donabedian holds a B.A. in Chemistry from St. Anselm College, a Ph.D. in Polymer Chemistry from the University of Massachusetts Lowell, and an MBA from the University of North Carolina.

Asha M. George, DrPH (invited) is the Executive Director of the Bipartisan Commission on Biodefense. She served on the Biden-Harris Transition Team and as a subcommittee staff director and senior professional staff for the US House of Representatives Committee on Homeland Security. She is a public health and national security expert.

Dylan George, Ph.D. is a Vice President at Ginkgo Bioworks where he is helping to develop improved biosecurity, surveillance, analytics, and capabilities to better engineer organisms. Prior to Ginkgo, Dr. George was a Vice President at In-Q-Tel (IQT) and held various positions in the United States Federal government (DoD, HHS, OSTP) where he developed analytics, promoted authorities, coordinated budgets, and enabled policies for better pandemic response and preparedness capabilities.

Peter Haaland, Ph.D. is a freelance applied scientist and inventor solving transdisciplinary problems by way of IARPA, DARPA, the USAF, early-stage VC, and diverse advisory activities in government and industry.

Dan Hanfling, MD is a Vice President on the Technical Staff at In-Q-Tel and a practicing emergency physician with expertise in operational emergency medicine. Prior to coming to In-Q-Tel he spent four years at HHS/ASPR, and before that led healthcare emergency management efforts for the Inova Health System (Falls Church, VA). He currently co-chairs the National Academy of Medicine's Forum on Medical and Public Health Preparedness.

Matthew Hepburn, MD is the Director of COVID Vaccine Development for the HHS-DoD Countermeasures Acceleration Group (formerly known as Operation Warp Speed). Prior to this he served as the Joint Project Lead for Enabling Biotechnologies for the Joint Program Office for Chemical, Biological, Radiological and Nuclear Defense (DoD), was a Program Manager at DARPA (2013-2019), and served as the Director of Medical Preparedness on the White House National Security Staff (2010-2013).

Amy Jenkins, Ph.D. joined DARPA as a Program Manager in June 2019. Her interests include the development of platforms for combatting infectious disease threats as well as novel manufacturing methods to enable rapid response. Prior to joining DARPA as a PM, Dr. Jenkins was a Senior Scientist at Gryphon Schafer where she contributed to development of programs targeting infectious disease threats within BTO. Prior to supporting DARPA, Dr. Jenkins studied the virulence factors of, and antibodies targeting, multi-drug resistant bacterial pathogens at MedImmune. She also served as a National Research Council Postdoctoral Fellow at the United State Army Medical Research Institute of Infectious Diseases where she studied virulence mechanisms of biodefense pathogens. She received her Doctor of Philosophy degree in Chemistry and Chemical Biology from Cornell University and her Bachelor of Science in Chemistry and Biomolecular Science from Clarkson University.

Robert Kadlec, MD is the former Assistant Secretary for Preparedness and Response at the Department of Health and Human Services and a member of Senator Richard Burr's (R-NC) staff.

14 🧵 The participants of this round table included: Georgetown [CIA prep school], CIA's IQT, Former CIA, Johns Hopkins Center for Health Security, BSL3 Universities: Wisconsin-Madison & UNC Chapel Hill, NARMU, ARMY, ASPR, MIT, Google, Clinton Foundation & DARPA...

He spent more than 20 years as a career officer and physician in the United States Air Force before retiring as a Colonel. Over the course of his career, he has held senior positions in the White House, the U.S. Senate, and the Department of Defense. He holds a bachelor's degree from the United States Air Force Academy, Doctorate of Medicine and Masters of Tropical Medicine and Hygiene from the Uniformed Services University of the Health Sciences, and Master's in National Security Studies from Georgetown University.

Kathryn Kosuda, Ph.D. is co-founder and CSO at Vaxess Technologies, a life science company focused on improving the efficacy and accessibility of vaccines using MIMIX™, a novel stabilization and skin delivery platform. Kathryn holds a PhD in Physical Chemistry from Northwestern University, did her postdoctoral research in the Department of Chemistry & Chemical Biology at Harvard, and began her career in pharmaceutical R&D at Merck Research Laboratories.

James Lawler, MD, MPH is Executive Director for International Programs and Innovation for the Global Center for Health Security at at the University of Nebraska Medical Center. He is also an Associate Professor of Medicine in Infectious Disease and Deputy Medical Director for the Nebraska Biocontainment Unit. Before joining the UNMC team in November 2017, he served 21 years in the US Navy Medical Corps. Dr. Lawler's work has spanned a broad array of research, policy, and field activities related to emerging and high-consequence infectious diseases, medical and public health preparedness, pandemic and outbreak response, and global health. Dr. Lawler served in national policy positions in both the White House Homeland Security Council Biodefense Office and the National Security Council Resilience Directorate spanning two administrations.

James Lim is a Summer Investment Associate at In-Q-Tel, focusing on the biotechnology/healthcare and enterprise technology sectors. He is a fourth-year JD/MBA candidate at Harvard Business School and Harvard Law School, and holds a B.A. in Economics from Harvard College.

W.B. "Mitch" Mitchell currently serves as Group Vice President, Government Solutions with Amwell. Mitch is a senior strategy and management professional with over 25 years passionately building businesses in healthcare and information technology. He combines expertise in Military and Veteran's Health, Telemedicine, Federal Health Programs, Patient Engagement and Clinical eHealth Strategy Development. Before joining Amwell, Mitch led Government Solutions for Ciox Health and for 15 years prior, Mitch led teams across McKesson/RelayHealth and Change Healthcare, supporting complex commercial and federal health IT, HIE and patient engagement programs.

Kevin O'Connell, Ph.D. is Vice President and Technical Co-Lead for B.Next, the IQT technology practice focused on life sciences and the intersection of biotechnology, healthcare, and national security. Prior to joining IQT, he was a researcher and principal investigator with the U.S. Army Edgewood Chemical Biological Center for 10 years, where he focused on pathogen detection and

genetic characterization. He holds a bachelor's degree in life sciences from MIT, and MS and PhD degrees in bacteriology from the University of Wisconsin-Madison.

Tara O'Toole, MD, MPH was Executive VP and Senior Fellow at IQT since 2014 and is now an IQT Sr. Fellow. She served as Under Secretary of Science and Technology at the Department of Homeland Security from 2009-14 and Assistant Secretary of Energy from1993-97. She was a founding member and Director of the organization now known as the Johns Hopkins Center for Health Security and professor of medicine and public health for the previous decade.

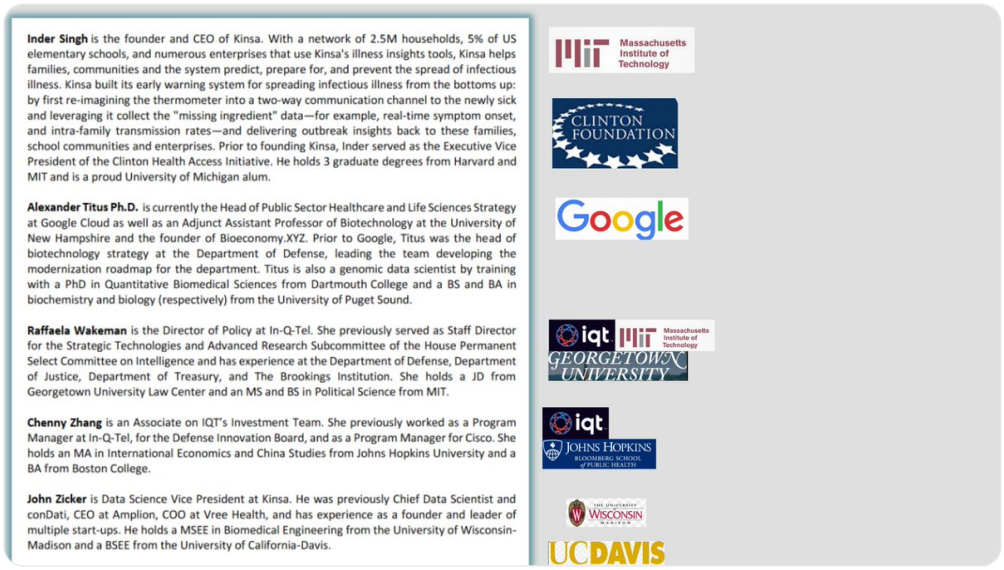
Sandeep Patel, Ph.D, is the Director of BARDA's Division of Research, Innovation, and Ventures (DRIVe). Prior to DRIVe, he founded KidneyX and PreventionX at the Department of Health and Human Services. He holds a Ph.D. from Georgia Tech and a B.S. from Washington University in St. Louis.

Martijn Rasser is a senior fellow and director of the Technology and National Security Program at the Center for a New American Security (CNAS). Prior to joining CNAS, he was an executive at an AI startup and a hedge fund. He is a former CIA officer.

Lewis Rubinson, MD, PhD is the Chief Medical Officer of Morristown Medical Center (MMC) within the Atlantic Health System (AHS). Dr. Rubinson is a critical care physician and the physician executive lead for the COVID-19 response at MMC, which was one of the early impacted referral hospitals. At the peak of the COVID-19 surge in the of Spring 2020, MMC had 20 COVID-19 inpatient units with more than 300 inpatients and more than 100 persons requiring mechanical ventilation. MMC has cared for nearly 3500 hospitalized persons with COVID-19 and AHS for nearly 8500 hospitalized patients. AHS has administered thousands of doses of monoclonal abs, hundreds of thousands of vaccination doses, enrolled 100s of patients in therapeutic trials and has implemented numerous testing platforms for COVID-19/ SARS-CoV-2.

Patrick Rose, Ph.D. is the Program Manager for the Department of Defense Bioindustrial Manufacturing Innovation Institute: BioMADE. In this role, he represents the government in a public-private partnership to address the spectrum of manufacturing challenges associated with biomanufacturing of non-medical products. He also serves as Science Director for Synthetic Biology at the U.S. Office of Naval Research Global in London, United Kingdom. In his position, Dr. Rose is responsible for maintaining a global network throughout the synthetic biology community and provides general technology awareness to the US Navy.

Sarah Sewall Ph.D. is the Executive Vice President for Policy at In-Q-Tel. From 2014-2017, she served as Under Secretary of State for Civilian Security, Democracy and Human Rights. During the Clinton Administration, she served as the inaugural Deputy Assistant Secretary of Defense for Peacekeeping. Dr. Sewall taught at Harvard for over a decade, where she directed the Carr Center for Human Rights Policy and worked closely with the U.S. military to advance civilian protection in war.



Inder Singh is the founder and CEO of Kinsa. With a network of 2.5M households, 5% of US elementary schools, and numerous enterprises that use Kinsa's illness insights tools, Kinsa helps families, communities and the system predict, prepare for, and prevent the spread of infectious illness. Kinsa built its early warning system for spreading infectious illness from the bottoms up: by first re-imagining the thermometer into a two-way communication channel to the newly sick and leveraging it collect the "missing ingredient" data—for example, real-time symptom onset, and intra-family transmission rates—and delivering outbreak insights back to these families, school communities and enterprises. Prior to founding Kinsa, Inder served as the Executive Vice President of the Clinton Health Access Initiative. He holds 3 graduate degrees from Harvard and MIT and is a proud University of Michigan alum.

Alexander Titus Ph.D. is currently the Head of Public Sector Healthcare and Life Sciences Strategy at Google Cloud as well as an Adjunct Assistant Professor of Biotechnology at the University of New Hampshire and the founder of Bioeconomy.XYZ. Prior to Google, Titus was the head of biotechnology strategy at the Department of Defense, leading the team developing the modernization roadmap for the department. Titus is also a genomic data scientist by training with a PhD in Quantitative Biomedical Sciences from Dartmouth College and a BS and BA in biochemistry and biology (respectively) from the University of Puget Sound.

Raffaela Wakeman is the Director of Policy at In-Q-Tel. She previously served as Staff Director for the Strategic Technologies and Advanced Research Subcommittee of the House Permanent Select Committee on Intelligence and has experience at the Department of Defense, Department of Justice, Department of Treasury, and The Brookings Institution. She holds a JD from Georgetown University Law Center and an MS and BS in Political Science from MIT.

Chenny Zhang is an Associate on IQT's Investment Team. She previously worked as a Program Manager at In-Q-Tel, for the Defense Innovation Board, and as a Program Manager for Cisco. She holds an MA in International Economics and China Studies from Johns Hopkins University and a BA from Boston College.

John Zicker is Data Science Vice President at Kinsa. He was previously Chief Data Scientist and conDati, CEO at Amplion, COO at Vree Health, and has experience as a founder and leader of multiple start-ups. He holds a MSEE in Biomedical Engineering from the University of Wisconsin-Madison and a BSEE from the University of California-Davis.

15 🧵 Representing DARPA in that round table was Matt Hepburn, project offer for DARPA's Adept/ Pandemic Prevention Platform [P3], & Fellow at Georgetown's Center for health security. He's behind the 60 day vaccine initiative for DARPA & Disease X.

Col. Matthew Hepburn, M.D.

Center Affiliate

Col. Matthew Hepburn, M.D., is currently assigned to DARPA as a program manager, since 2013. Prior to joining DARPA, Col. Hepburn served as the Director of Medical Preparedness on the White House National Security Staff. Additional previous assignments include: Chief Medical Officer at a Level II medical facility in Iraq, clinical research director at the US Army Medical Research Institute for Infectious Diseases, exchange officer to the United Kingdom and internal medicine chief of residents at Brooke Army Medical Center at Fort Sam Houston, Texas.

Col. Hepburn completed internal medicine residency and infectious diseases fellowship programs at Brooke Army Medical Center. He holds Doctor of Medicine and Bachelor of Science in biomedical engineering degrees from Duke University.

DARPA DEFENSE ADVANCED RESEARCH PROJECTS AGENCY

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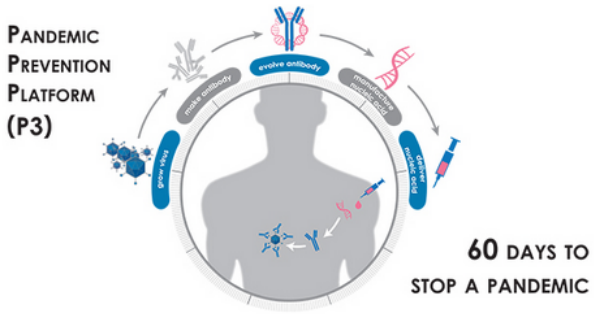
Defense Advanced Research Projects Agency › Removing the Viral Threat: Two Months to Stop Pandemic X from Taking Hold

Removing the Viral Threat: Two Months to Stop Pandemic X from Taking Hold

DARPA aims to develop an integrated end-to-end platform that uses nucleic acid sequences to halt the spread of viral infections in sixty days or less

OUTREACH@DARPA.MIL
2/6/2017



Over the past several years, DARPA-funded researchers have pioneered RNA vaccine technology, a medical countermeasure against infectious diseases that uses coded genetic constructs to stimulate production of viral proteins in the body, which in turn can trigger a protective antibody response. As a follow-on effort, DARPA funded research into genetic constructs that can directly stimulate production of antibodies in the body.[1,2] DARPA is now launching the Pandemic Prevention Platform (P3) program, aimed at developing that foundational work into an entire system capable of halting the spread of any viral disease outbreak before it can escalate to pandemic status. Such a capability would offer a stark contrast to the state of the art for developing and deploying traditional vaccines—a process that does not deliver treatments to patients until months, years, or even decades after a viral threat emerges.

"DARPA's goal is to create a technology platform that can place a protective treatment into health providers' hands within 60 days of a pathogen being identified, and have that treatment induce protection in patients within three days of administration. We need to be able to move at this speed considering how quickly outbreaks can get out of control," said Matt Hepburn, the P3 Program Manager. "The technology needs to work on any viral disease, whether it's one humans have faced before or not."

Recent outbreaks of viral infectious diseases such as Zika, H1N1 influenza, and Ebola have cast into sharp relief the inability of the global health system to rapidly contain the spread of a disease using existing tools and procedures. State-of-the-art medical countermeasures typically take many months or even years to develop, produce, distribute, and administer. These solutions often

16🧵 Lastly, JHCHS in April of 2020 at the start of the Pandemic wrote a proposal to Congress urging congress for "A new dedicated Virus 201 strategy, program, & funding must be created to achieve this goal
through HHS's BARDA, the DODs Joint Program Executive Office for Chemical and Biological Defense (JPEO), In-Q-Tel & DARPA"

The Virus 201 Medical Countermeasure Strategy should be coordinated through the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), led by HHS ASPR and DOD JPEO, with each agency supporting product candidates that best meet the needs of the populations they serve. PHEMCE must ensure collaboration with DARPA and In-Q-Tel.

Virus 201 Medical Countermeasures Strategy

Virus 201 means a previously unidentified viral threat, whether naturally occurring or man-made. These pathogens can affect both military personnel and the American public. DOD and HHS investment strategies should be coordinated through PHEMCE, with DOD taking the lead on products targeted to protect young, healthy military personnel, and HHS leading on other products needed to protect the diverse American public, including children and other vulnerable populations.

Since Virus 201 medical countermeasures may not have a commercial market that drives private sector investment, it is essential that a sustainable public-private partnership model and dedicated funding be created to share the development risk, incentivize development of new medical countermeasures, and invest in faster capabilities to respond to potential pandemics. Such countermeasures may include:

- **Antivirals:** In the time before a vaccine is available, antiviral treatments must be developed and deployed to decrease complications, hospitalizations, contagiousness, and mortality. Novel antiviral therapies range from small molecules to monoclonal antibody–based products. Under this proposed Virus 201 Medical Countermeasure Strategy, several kinds of antiviral therapies should simultaneously be supported.

- **Vaccines:** Vaccines are the best solution to protecting Americans from novel viruses, but they usually take the longest to develop. Vaccine technologies have progressed in recent years to include several promising platform technologies that can be more quickly leveraged once a threat has been characterized. More can be done to develop better and faster vaccine platform technologies as well as next-generation manufacturing capabilities that enable faster response.

COVID-19 Proposal:

Funding for New Initiatives at HHS and DOD to Rapidly Develop Medical Countermeasures for Novel Infectious Diseases in Months, Not Years

Problem

Today's COVID-19 pandemic is an undeniable example of an increasing global trend of deadly infectious disease outbreaks. More than 200,000 people are dead, communities are shut down, and huge economic losses are occurring around the world. The profound effects of this pandemic must galvanize the US government to do everything in its power to prevent this from happening again. With nearly 200 epidemics occurring each year, the next fast-moving, novel infectious disease pandemic—Virus 201—could be right around the corner.

Our best defense is safe and effective medical countermeasures: drugs, vaccines, and diagnostics. However, the development of these life-saving products still takes years.

When the next deadly pathogen emerges, the United States needs to move much faster to develop and deploy medical countermeasures. Existing programs at HHS and DOD are primarily directed toward specific known, high-priority health security threats (including chemical, biological, radiological, and nuclear threats, and pandemic influenza). There is no sustained funding, program, or strategy dedicated to accelerating the development of medical countermeasures for previously unidentified infectious disease threats, referred to here as Virus 201.

Proposal

The United States must set an ambitious goal of rapidly developing medical countermeasures for novel or unknown threats in months, not years. Innovative technologies, outside-the-box thinking, and game-changing science must be harnessed to meet this goal.

A new dedicated Virus 201 strategy, program, and funding must be created to achieve this goal

April 30, 2020 – Today's COVID-19 pandemic is an undeniable example of an increasing global trend of deadly infectious disease outbreaks. More than 200,000 people are dead, communities are shut down, and huge economic losses are occurring around the world. The profound effects of this pandemic must galvanize the US government to do everything in its power to prevent this from happening again. With nearly 200 epidemics occurring each year, the next fast-moving, novel infectious disease pandemic—Virus 201—could be right around the corner.

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The United States must set an ambitious goal of rapidly developing medical countermeasures for novel or unknown threats in months, not years. Innovative technologies, outside-the-box thinking, and game-changing science must be harnessed to meet this goal.

The Center for Health Security calls for a new dedicated Virus 201 strategy and program, and funding must be created to achieve this goal through the HHS Biomedical Advanced Research and Development Authority (BARDA) and the DOD Joint Program Executive Office for Chemical and Biological Defense (JPEO). This strategy should not compete with or cannibalize other important medical countermeasure development efforts focused on specific known threats, and it should involve other innovative agencies like DARPA and In-Q-Tel.

Therefore, a new congressional appropriation of $1 billion, divided equally between HHS and DOD, should be provided to enable these agencies to initiate a robust and coordinated strategy to accomplish this goal before the next virus threatens the globe.

17🧵 Those are either some FANTASTIC coincidences or some serious RICO case evidence against these aforementioned entities for their obvious involvement as an undefined criminal organization. Links for ALL will be in the comments. Thank you for reading!🙏

Wait, I forgot to tell you. In 2017, when Metabiota and EcoHealth Alliance [EHA]were being Shuffled around China by USAID, Kevin Olival of EHA worked with In-Q-Tel on another vaccine/disease testing roundtable.😳

4. Regulatory issues remain, and behind them lurk all of the business hurdles inherent to new diagnostic technologies: low return on investment, uncertain reimbursement structures, and the need to educate users (from clinical labs to the bedside) in their operation and the interpretation of sequence data. Public health could leverage a data stream from in-clinic use of portable sequencers, but getting portable DNA sequencing into the clinical setting will require its approval as a diagnostic technology. The regulatory environment is slowly evolving to cover this technology; a recent example (Dec 2016) of a next generation sequencing test receiving FDA approval for use as a companion diagnostic is FoundationFocus™ CDx_{BRCA} from Foundation Medicine for the qualitative detection of *BRCA 1/2* alterations for ovarian cancer therapeutics[1] and the recently approved Oncomine Dx Target Test from Thermo Fisher[2].

5. The exploitation of portable sequencing in the field during epidemics urgently requires new tools for collaboration among operators at widely dispersed locations. One example of such a tool is Nextstrain (nextstrain.org), which is an effort to create a portal that can allow scientists to analyze and dynamically visualize new data as they are received from

[1] http://investors.foundationmedicine.com/releasedetail.cfm?ReleaseID=1004896
[2] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160045

fielded DNA sequencers. Such portals should also facilitate the distribution of updated information based on near-real-time genome evolution tracking.

The Roundtable included experts from industry, academia, finance and several USG agencies who manufacture, consume, invest in, or develop use cases for sequencing applications as they relate to disease outbreaks. The discussion took place over a single day, included invited presentations from four participants plus prepared remarks from three others (see below), and was held on a not-for-attribution basis. (The participants agreed to allow IQT to publish a summary of key insights from the meeting. In addition, participants named below consented to allow us to use their names in this report.)

Summary of Discussion

The discussion at this round table was organized to discuss three questions:

1. What might be specific applications of portable sequencers for infectious disease detection and management? This discussion was opened with presentations on potential use cases from Kevin Olival of the Eco-Health Alliance (on pathogen discovery prior to outbreaks), Trevor Bedford of the Fred Hutchinson Cancer Center (on sequencing during outbreaks to track the origin and evolution of pathogens during outbreaks), and Alan Rudolph of Colorado State University (on sequencing applications in food safety, agriculture and soil quality).

2. What operational characteristics, performance metrics, and supporting technology or infrastructure will make portable sequencers more applicable to the problem? This discussion began with an in-depth briefing from James Brayer of Oxford Nanopore (on the current capabilities of the MinION sequencer), and from Sterling Thomas of Noblis, Inc (on bioinformatics-related challenges to fieldable sequencing).

2. What operational characteristics, performance metrics, and supporting technology or infrastructure will make portable sequencers more applicable to the problem? This discussion began with an in-depth briefing from James Brayer of Oxford Nanopore (on the current capabilities of the MinION sequencer), and from Sterling Thomas of Noblis, Inc (on bioinformatics-related challenges to fieldable sequencing).

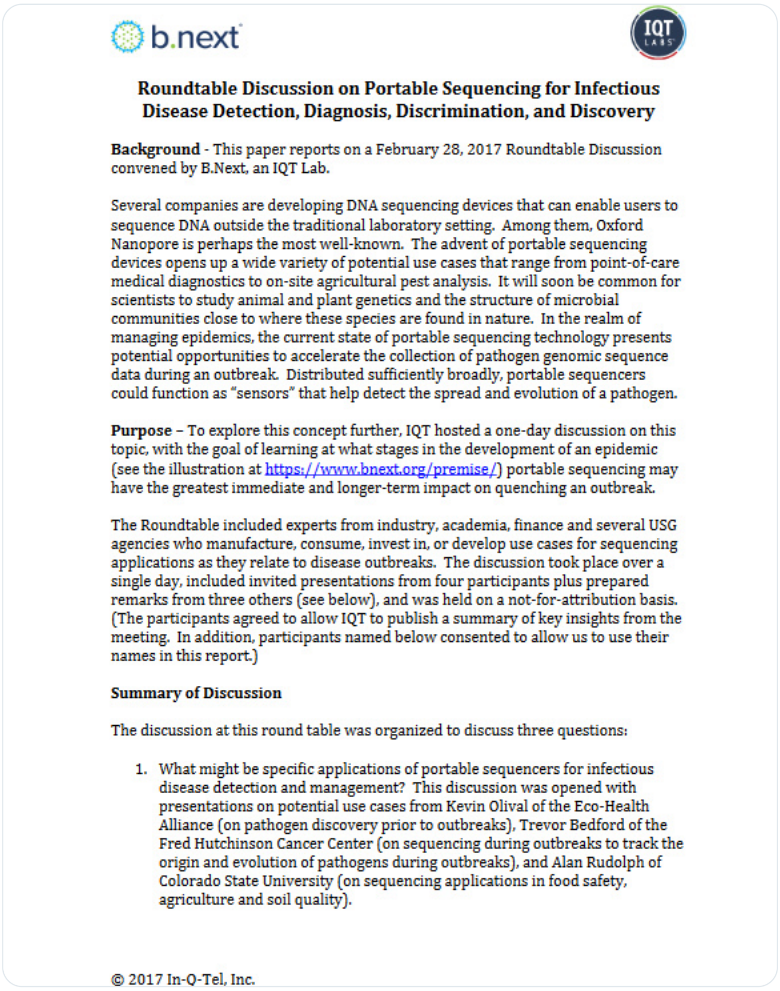
3. What are the market drivers and opportunities? Alex de Winter of GE Ventures and Mickey Urdea of Halteres Associates opened this section with discussions of the investment challenges associated with diagnostics technologies.

Discussion Topics

Several key take-away messages emerged from the discussion:

1) **The technology.** Portable sequencing is here. The quality and quantity of data generated by MinION are substantially improved over just a year ago, and will continue to improve. Oxford Nanopore has a tremendous first-to-market advantage, but we know of and expect other vendors to enter the market. James Brayer of Oxford Nanopore gave an update on the current specifications of MinION sequencers. The devices have seen a significant jump in the accuracy in base-calling, which is now in the low 90%'s. This is still lower than the 99+% of Illumina systems, but the quality of sequence is ramping quickly, and attendees noted that there is value to being able to quickly sequence a sample on-site and transmit data, rather than transport a sample. MinION is beginning to realize that potential.

2) **The importance of accuracy and sensitivity.** The sequencing accuracy issue is part of a larger conversation on the problem of false positive and false negative results. Other contributors to false positive results include the incompleteness of reference data for comparative purposes and the presence of microorganisms that are "conditional" or "opportunistic" pathogens (e.g. *Staphylococcus aureus*, *Clostridium difficile*), meaning they may be present without causing a disease, but may become pathogenic upon a change in conditions (e.g. immune status, nutritional state). A false negative result may occur due to the throughput of the sequencer when processing samples in which the pathogen's genome is a small fraction of the total DNA or RNA in a sample. For example, in a clinical sample, the vast majority of DNA molecules will be host DNA. Sequencing the pathogen will therefore require sequencing a large excess of host DNA molecules to accumulate enough pathogen sequence to assemble a genome, unless techniques are employed prior to sequencing to enrich the pathogen-specific nucleic acids. Another contributor to false negative results is the characteristic of some pathogens residing in anatomically inaccessible reservoirs, such as cryptosporidium that burrow into the intestinal wall. Sensitivity and accuracy thresholds,



b.next

Roundtable Discussion on Portable Sequencing for Infectious Disease Detection, Diagnosis, Discrimination, and Discovery

Background - This paper reports on a February 28, 2017 Roundtable Discussion convened by B.Next, an IQT Lab.

Several companies are developing DNA sequencing devices that can enable users to sequence DNA outside the traditional laboratory setting. Among them, Oxford Nanopore is perhaps the most well-known. The advent of portable sequencing devices opens up a wide variety of potential use cases that range from point-of-care medical diagnostics to on-site agricultural pest analysis. It will soon be common for scientists to study animal and plant genetics and the structure of microbial communities close to where these species are found in nature. In the realm of managing epidemics, the current state of portable sequencing technology presents potential opportunities to accelerate the collection of pathogen genomic sequence data during an outbreak. Distributed sufficiently broadly, portable sequencers could function as "sensors" that help detect the spread and evolution of a pathogen.

Purpose – To explore this concept further, IQT hosted a one-day discussion on this topic, with the goal of learning at what stages in the development of an epidemic (see the illustration at https://www.bnext.org/premise/) portable sequencing may have the greatest immediate and longer-term impact on quenching an outbreak.

The Roundtable included experts from industry, academia, finance and several USG agencies who manufacture, consume, invest in, or develop use cases for sequencing applications as they relate to disease outbreaks. The discussion took place over a single day, included invited presentations from four participants plus prepared remarks from three others (see below), and was held on a not-for-attribution basis. (The participants agreed to allow IQT to publish a summary of key insights from the meeting. In addition, participants named below consented to allow us to use their names in this report.)

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SOURCES:

Darby^

INQTEL^

Aug 22, 2023

In-Q-Tel, 2021

IQT Roundtable: Capabilities Required for Pandemic Response – August 2021

ROUNDTABLE REPORT – LEVERAGING DIGITAL HEALTH TECHNOLOGIES DURING LARGE-SCALE EPIDEMICS

December 2019:

IQT Nanopore+EHA Kevin Olival Feb 2017 rountable:

Delivering the biorevolution: a BNext Workshop on cellular delivery technologies November 5, 201

Roundtable Discussion on Portable Sequencing for Infectious
Disease Detection, Diagnosis, Discrimination, and Discovery
Background - This paper reports on a February 28, 2017 Roundtable Discussion convened by , an IQT Lab:

Destiny Rezendes
@dezzie_rezzie · **Follow**

Replying to @dezzie_rezzie

2 🧵The report was written in Dec.2019 by the CIA's venture capital arm, In-Q-Tel & was a summary of their round-table meeting held Dec 5th 2019 titled; LEVERAGING DIGITAL HEALTH TECHNOLOGIES DURING LARGE-SCALE EPIDEMICS

b.next IQT

ROUNDTABLE REPORT – LEVERAGING DIGITAL HEALTH TECHNOLOGIES DURING LARGE-SCALE EPIDEMICS

December 2019

Introduction

The capabilities required to manage a large-scale epidemic are multifaceted, complex and range across a number of critical domains – the ability to detect and recognize the presence of disease in the community; the capacity to design, manufacture and deliver life-saving medical countermeasures, including therapeutics and vaccine; and the process by which healthcare services can be delivered to the population-in-need in a scalable fashion that maintains the highest possible standard of care.

Background

In-Q-Tel/B.Next convened a Roundtable meeting, held on December 5, 2019 in Arlington, VA to explore the role digital health technologies can play to support the response to large infectious disease outbreaks. Roundtable participants included experts drawn from several United States (U.S.) Government agencies, academia, private-sector technology companies and members of the In-Q-Tel and B.Next team. The discussion took place over a single day. There were two invited presentations, and the meeting was conducted on a not-for-attribution basis.

This Roundtable discussion was the first of a series of meetings which intend to explore how digital health technologies might be applied to epidemic management. This meeting was focused expressly on two broad themes -- the role enabling technologies can play in allowing the population to initiate self-triage, and how such technologies might aid in preserving the integrity of hospital services over the course of an extended outbreak event. Subsequent Roundtable discussions in this series will explore the potential of these technological platforms to help provide appropriate medical treatment in an austere environment where resources are scarce. We will also examine how digital health technologies might enable the collection, analysis and coordination of data in order to provide essential situational awareness, thereby facilitating the creation of a "learning healthcare system" in the midst of an epidemic crisis.

8:43 PM · Aug 22, 2023

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https://www.gpmb.org/about-us#tab=tab_2

Intelligence report says US split on Covid-19 origins

A declassified report finds no direct evidence the virus came from a lab, but adds it can't be ruled out.

https://www.bbc.com/news/world-us-canada-66005240

https://www.iqt.org/wp-content/uploads/2022/12/RT-FINAL-REPORT__09_18_21.pdf

https://www.iqt.org/wp-content/uploads/2022/12/Digital-Health-Roundtable-Report.pdf
https://www.iqt.org/wp-content/uploads/2022/12/Portable-Seq-RT-summary_final.pdf
https://centerforhealthsecurity.org/2020/johns-hopkins-center-for-health-security-calls-for-funding-for-new-initiatives-to-rapidly-develop-medical-countermeasures-for-novel-infectious
https://www.iqt.org/wp-content/uploads/2022/12/drugdeliveryFindings_nov5.pdf
https://centerforhealthsecurity.org/2020/johns-hopkins-center-for-health-security-calls-for-funding-for-new-initiatives-to-rapidly-develop-medical-countermeasures-for-novel-infectious
B.Next
https://www.iqt.org/wp-content/uploads/2022/12/Portable-Seq-RT-summary_final.pdf

• • •

Destiny Rezendes @dezzie_rezzie

Aug 9 • 21 tweets • dezzie_rezzie/status/1689373850985697280

1 🧵The Bill & Melinda Gates Foundation [BMFG] is a name that cannot be mentioned when discussing the Covid-19 pandemic. Although not a doctor nor was he a politician, Bill Gates' impact was monumental. He funded Baric's lab at UNC Chapel Hill. He was close with Dr. Fauci..

EurekAlert! | AAAS

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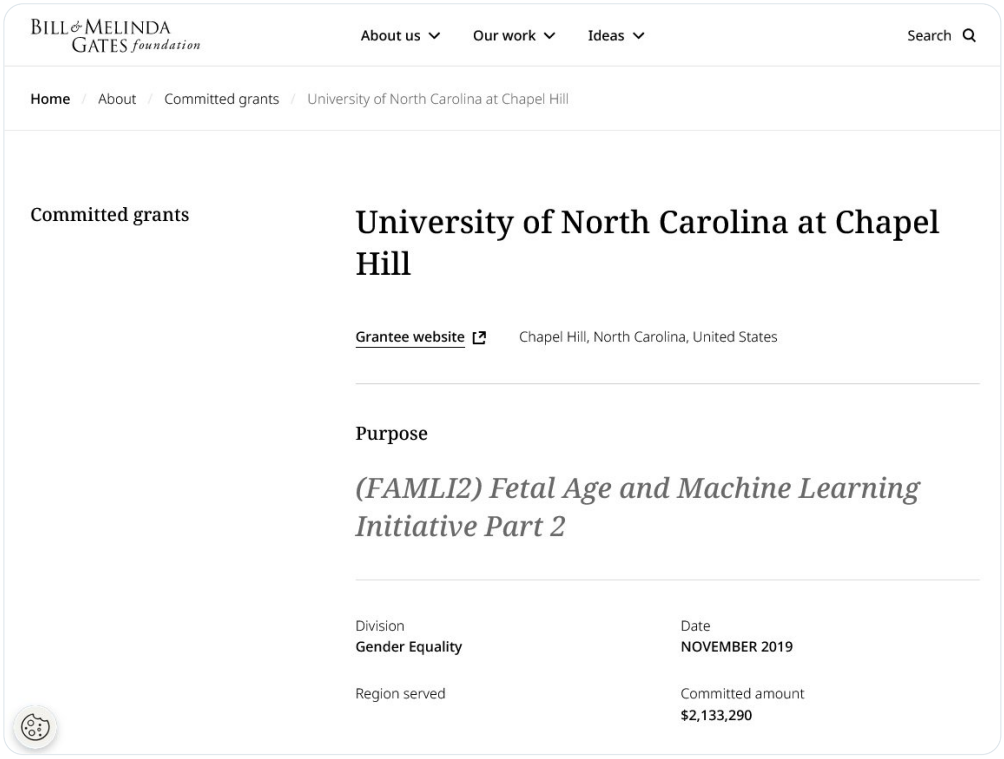
UNC receives $21.3 million Gates Foundation grant

Grant and Award Announcement

UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL

CHAPEL HILL -- The University of North Carolina at Chapel Hill has received a $21.3 million grant from the Bill & Melinda Gates Foundation to develop effective, inexpensive drugs to treat late-stage African sleeping sickness and visceral leishmaniasis – diseases that infect and kill hundreds of thousands of people in developing nations.

The grant supports the work of an international consortium led by Dr. Richard Tidwell, a professor in UNC's Schools of Medicine and Pharmacy and principal investigator for the project.



https://www.gatesfoundation.org › about › committed-grants › 2019 › 11 › inv003266

University of North Carolina at Chapel Hill | Bill & Melinda Gates ...

$2,133,290. **Grant** topic. MNCH Discovery and Tools. Duration (months) 29. Grantee location. **Chapel Hill**, North Carolina, United States. More about our work. Our story. Learn about the origins of the **foundation and** the values that drive our work. Learn more. Our work.

https://www.gatesfoundation.org › about › committed-grants › 2018 › 11 › inv-007382

University of North Carolina at Chapel Hill | Bill & Melinda Gates ...

Committed **grants**. More in this section Committed **grants**. Home; About; Committed **grants** ... University of North Carolina at **Chapel Hill** Grantee website **Chapel Hill**, North Carolina, United States Purpose (LABOR) Limiting Adverse Birth Outcomes in Resource-Limited Settings Grantee. Division. Gender Equality ... 1991-2023 **Bill** & **Melinda Gates** ...

2 🧵Gates had purchased immense power in the world of Public Health-founding/funding; GAVI, IAVI, Global Polio Eradicate Initiative GPEI, WHO, CDC, ResearchGate, Global Health Investment Fund & the OECD, Trinity Challenge, GinkoBioworks & In 2000 Gates started the ONE Campaign.

Building global commitment to fight poverty and disease

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In the fight against extreme poverty, hunger, and preventable disease around the globe, ONE plays a unique role. It uses its resources to make human crises and their solutions matter—to leaders, funders, private and public institutions, and millions of people worldwide.

ONE pursues its goals through policy advocacy, grassroots mobilization, communications, and creative campaigning. Among its more visible efforts are direct personal appeals by high-profile individuals—including ONE co-founder Bono—to world leaders to address urgent development issues and follow through on their aid commitments. ONE also mobilizes its 3.2 million members to pressure policymakers to increase their effort, accountability, and transparency in the fight against disease and poverty, particularly in Africa. By making the most of technology and social media, ONE has also become a leading force in educating the public about global health and development and in changing perceptions about aid and its impact.

ONE's Roots

ONE originated in conversations between Bill Gates and Bono in the early 2000s about the need to better inform Americans about extreme poverty around the world. Together with Melinda Gates, Bobby Shriver, George Soros, Ed Scott, Bob Geldof, and Jamie Drummond, they created an anti-poverty advocacy organization called DATA that focused on deploying celebrities and other influential individuals to urge world leaders to take action on specific development issues. Within a few years, DATA had joined with several other organizations to form ONE, with major backing from the Bill & Melinda Gates Foundation. The goal was to create a political constituency for development priorities—particularly the UN Millennium Development Goals, which in 2000 set specific global targets to address disease, poverty, and other pressing development issues.

Investors & Partners

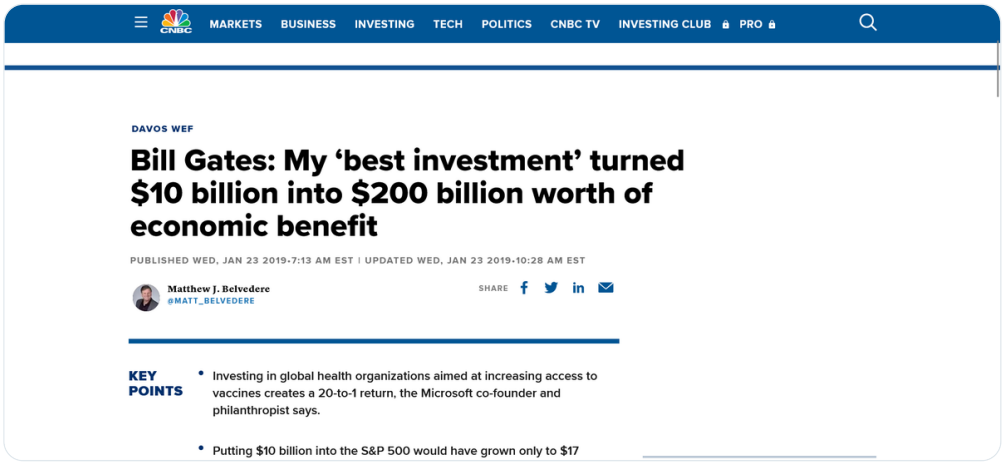
CEPI was founded in Davos by the governments of Norway and India, the Bill & Melinda Gates Foundation, Wellcome, and the World Economic Forum.

To date, CEPI has secured financial support from Australia, Austria, Belgium, the Bill & Melinda Gates Foundation, Canada, Denmark, the European Commission, Ethiopia, Finland, Germany, Greece, Hungary, Iceland, Indonesia, Italy, Japan, Kuwait, Lithuania, Luxembourg, Malaysia, Mexico, Netherlands, New Zealand, Norway, Panama, Portugal, Philippines, Romania, Saudi Arabia, Senegal, Serbia, Singapore, Switzerland, Republic of Korea, United Kingdom, USA, and Wellcome.

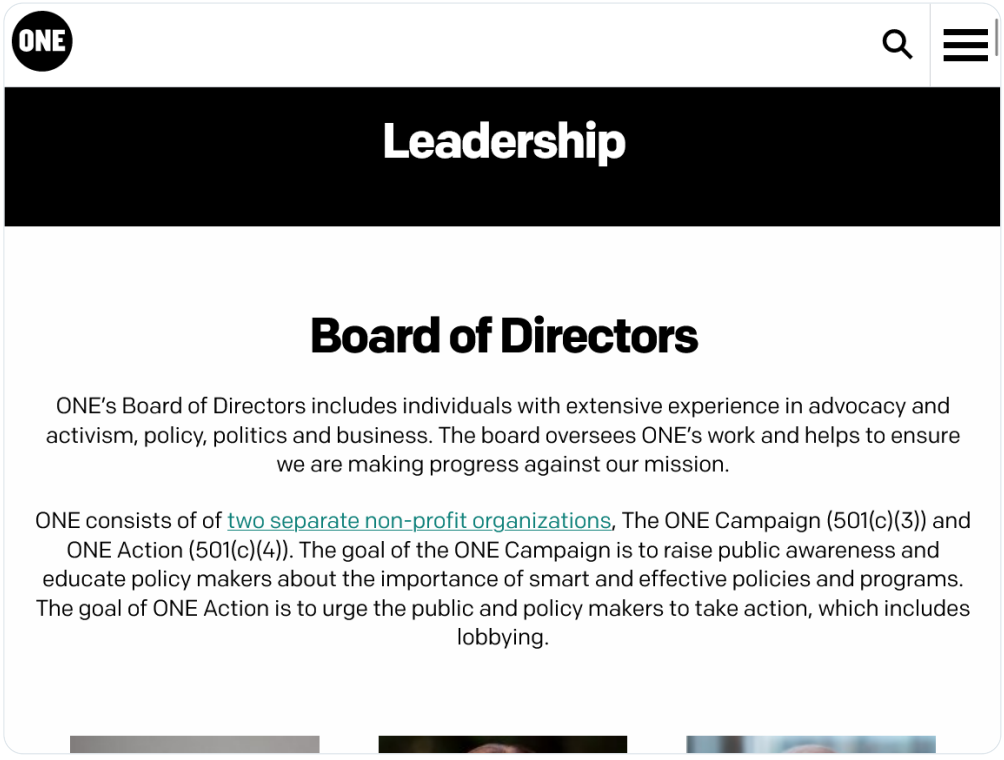
CEPI has also received support from private sector entities as well as public contributions through the UN Foundation COVID-19 Solidarity Response Fund.

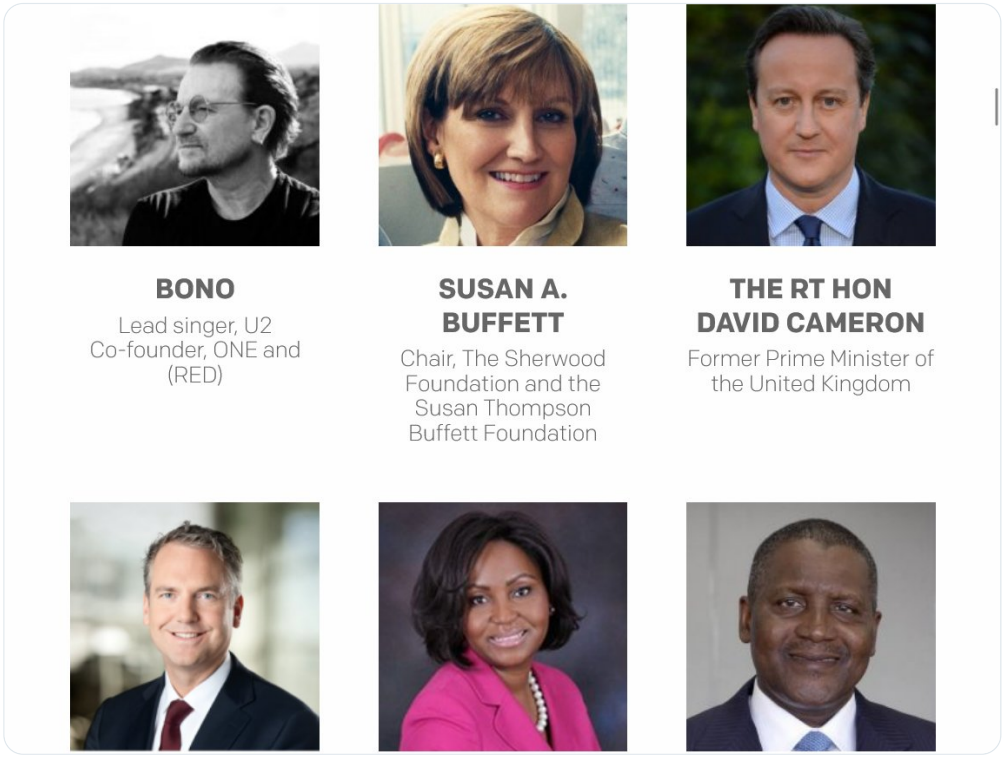
Close collaboration with our partners is crucial for the success of our work.

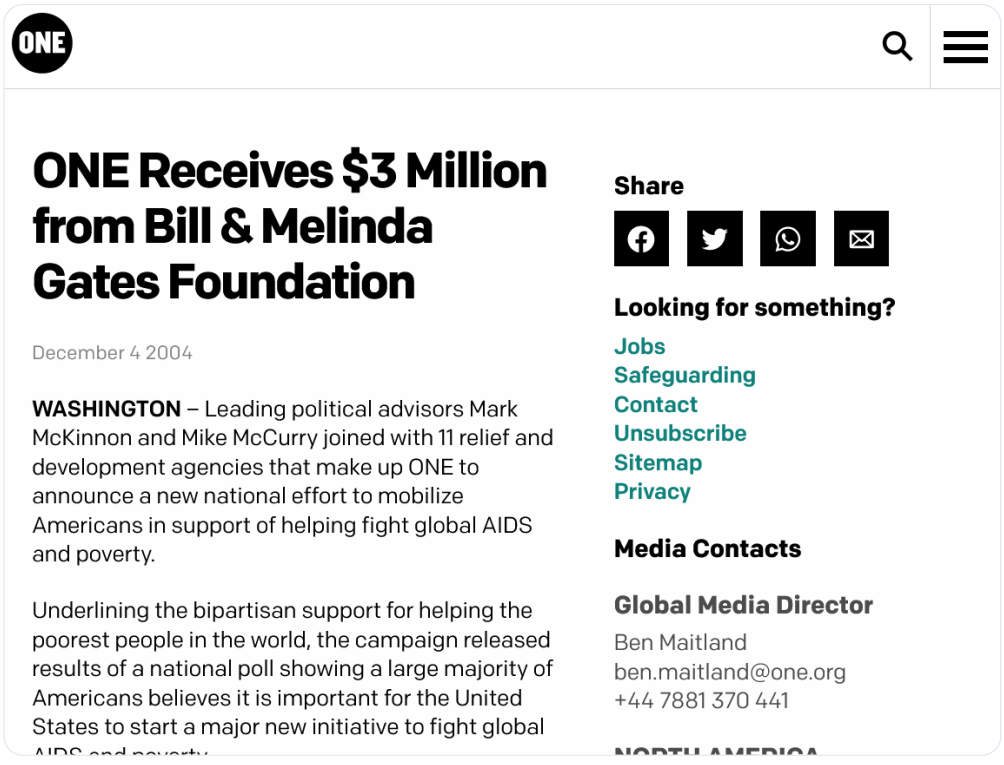
See our full list of contributions and pledges.



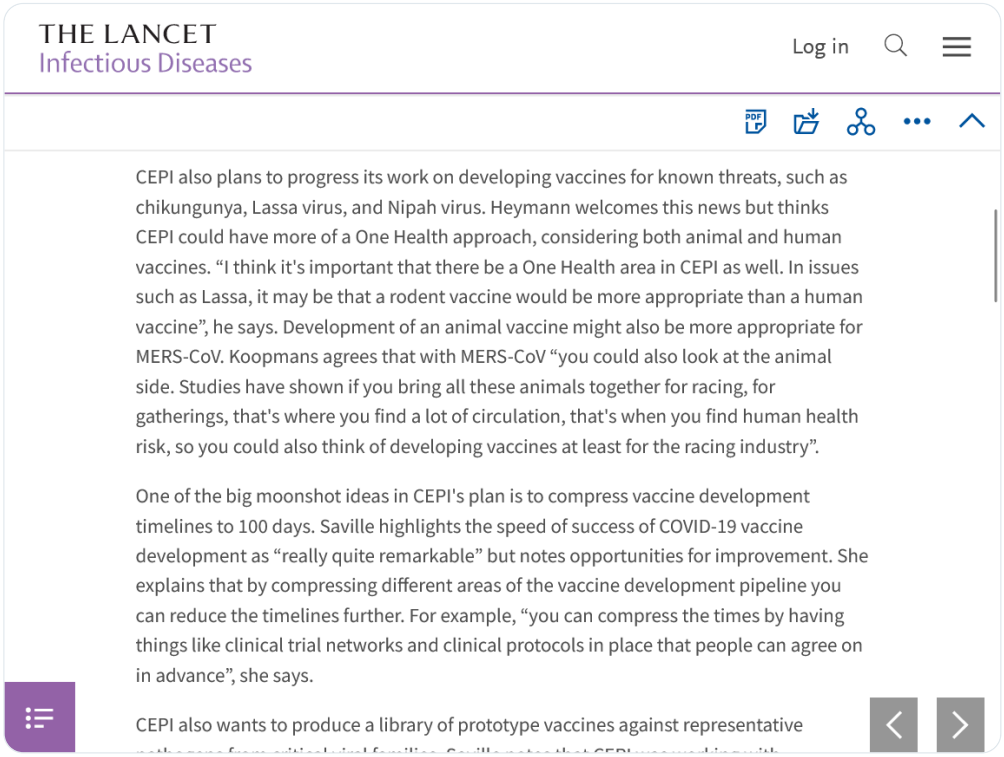
3🧵The ONE Campaign was about...Global Health! [of course] and was formed w/ Bobby Shriver, George Soros, & others & used celebrities like Bono and Lady Gaga to promote it. All of it in alignment with the UN Millennium Development Goals







4🧵In 2017 the BMGF along w/ Wellcome Trust, WEF, Norway & India, founded the Coalition of Epidemic Preparedness [CEPI] at Davos. Now Headquartered in Oslo, Norway. CEPI is a lead promoter of "OneHealth."



5🧵BMFG alongside JP Morgan Chase Bank founded the Global Health Investment Fund which works alongside the Global Health Investment Corporation in 2012, a founder of GHIC is also CEO for GHIF, long time corporate lawyer, and IAVI board member, Labeeb Abboud

GHIC GHIF

what specific types of COVID-19 programs have GHIF portfolio companies launched

Quick Search

GHIF portfolio companies have launched several types of COVID-19 programs. Here are some examples:

- Rapid COVID-19 tests: Atomo Diagnostics and AccessBio, both GHIF portfolio companies, have developed rapid COVID-19 tests that provide results in just minutes [1] [2]. These tests have been approved for use in several countries and are being used to help diagnose COVID-19 infections.
- CRISPR-based diagnostic test: GeneDrive, another GHIF portfolio company, is working on developing a CRISPR-based diagnostic test for COVID-19 [3]. The test would be able to detect the virus in saliva samples and provide results in just 30 minutes.
- Low-cost COVID-19 vaccine: Univercells, a GHIF portfolio company, is working on developing a low-cost COVID-19 vaccine that can be produced quickly and at scale [4]. The vaccine uses a technology called microfluidics to produce the vaccine in small, portable units that can be easily transported and deployed in low-resource settings.
- Other COVID-19-related programs: GHIF portfolio companies have also launched other COVID-19-related programs, although specific details are not provided in the search results. These programs may include the development of COVID-19 treatments, the production of personal protective equipment (PPE), or the deployment of other medical solutions to help address the pandemic.

Overall, GHIF portfolio companies have launched a range of COVID-19 programs, including rapid tests, diagnostic tests, vaccines, and other medical solutions. These programs demonstrate GHIF's commitment to investing in innovative technologies that have the potential to make a significant impact on global health outcomes, including in the context of the COVID-19 pandemic.

Global Health Investment Corporation

About Portfolio Partners News Careers

Global Health Investment Fund

Our namesake $108 million social impact fund (GHIF) invested in twelve companies developing clinical diagnostics, devices, vaccines, and therapeutics targeting diseases that disproportionately burden people living in low- and middle-income countries, such as HIV/AIDS, malaria, tuberculosis and cholera. The fund's portfolio companies have successfully commercialized more than a dozen products that have been delivered to over 100 million people.

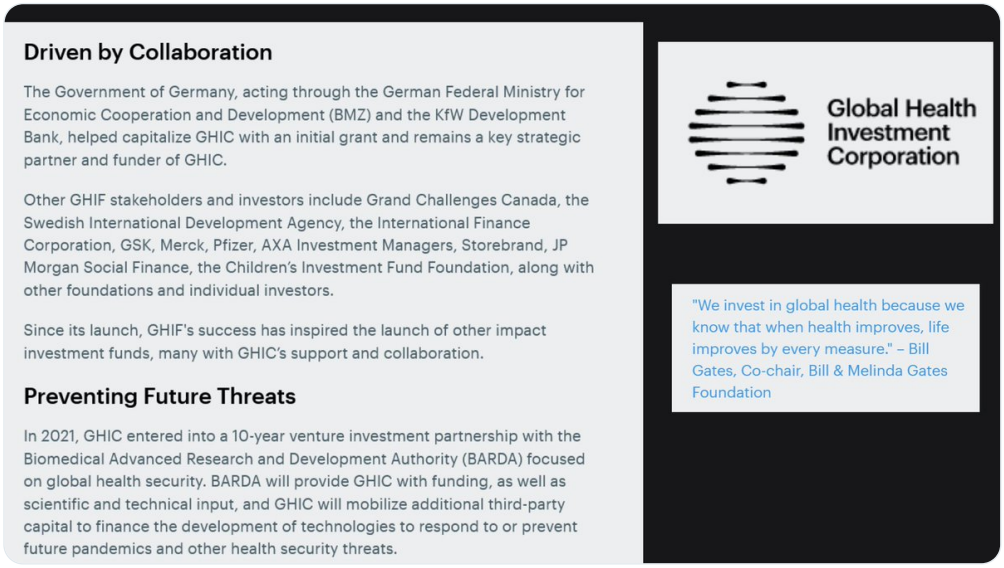
Global Health Investment Corporation

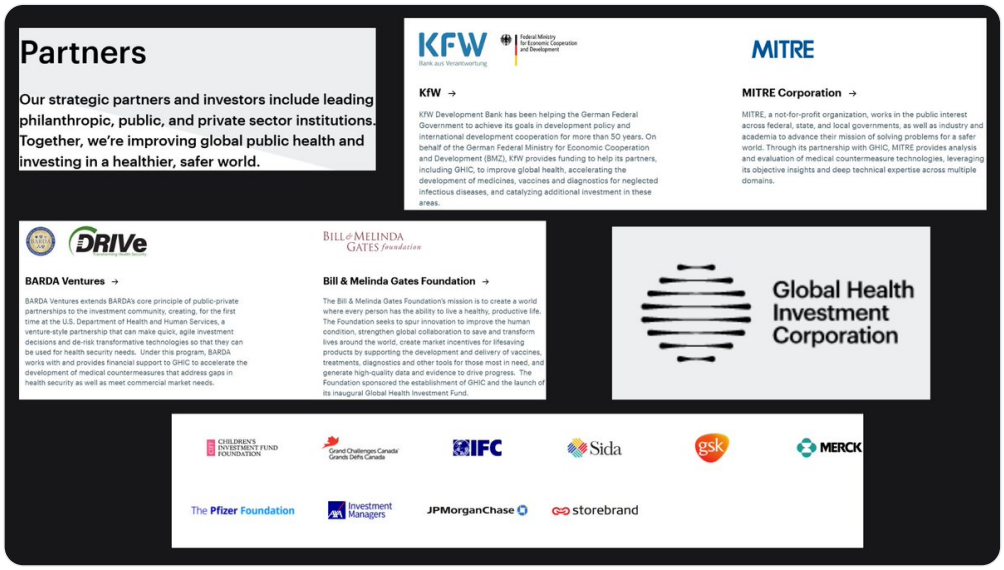
History

Inspired by Innovation

In 2012, the Bill & Melinda Gates Foundation sponsored the creation of GHIC and the launch of its initial fund, the Global Health Investment Fund, with the support of JP Morgan Chase. The original vision was to apply well-established venture capital practices using blended finance to accelerate the development of products and technologies that would improve lives globally by addressing high-burden global health challenges.

GHIF was started by Bill Gates & JP Morgan Chase





6🧵Abboud isn't the only name of interest at GHIC, as thee is also a former FTX member on the board [that's reassuring smh] More importantly, CEPI has massive conflicts of interest, besides board members like Richard Hatchett and Jane Halton there's the Joint Coordination Group-

LABEEB ABBOUD

General Counsel & Senior Vice President
Business Development & Strategy; Corporate Secretary

Labeeb M. Abboud provides leadership on legal affairs, business development, intellectual property, risk management, and innovative finance initiatives. He advises the Board of Directors and CEO on governance and strategy, and is board chair of the IAVI-UVRI HIV Vaccine Program in Uganda. He is principally responsible for structuring IAVI's collaborations and joint ventures with academic, industry, and public sector partners to ensure that any HIV vaccine developed will be globally accessible and affordable.

Abboud is Chairman of the Board of the Global Health Investment Fund, a Bill & Melinda Gates Foundation-sponsored social impact investment fund focused on accelerating late-stage development of vaccines, drugs, diagnostics, and devices to address global health challenges in developing countries. He also serves on the Expert Advisory Group of the Medicines Patent Pool, which seeks to increase access to HIV, viral Hepatitis C, and tuberculosis treatments in low- and middle-income countries.

Prior to joining IAVI in 2004, he had 20 years of experience in the fields of international law and finance. He is a member of the Council on Foreign Relations, and has also served on the boards of several non-profit organizations. He is a graduate of Wesleyan University and Georgetown University Law Center.

As of December 2017

Members of the Scientific Advisory Committee

Alan D. Barrett
University of Texas Medical Branch

Alash'le Abimiku
International Research Center of Excellence, Institute of Human Virology, Nigeria/ University of Maryland School of Medicine Institute of Human Virology

Azra Ghani
Imperial College London, UK

Marco Safadi
Santa Casa de Sao Paulo School of Medical Sciences, Brazil

Michael King
University of Virginia (SAC Vice Chair)

Michel De Wilde
MDW Consultant, LLC

Paula Bryant
National Institute of Allergy and Infectious Diseases, National Institutes of Health, USA

Peter Dull
Bill & Melinda Gates Foundation

Peter Paradiso
Paradiso Biologics Consulting LLC

Christian Drosten
Charité – Universitätsmedizin Berlin, Germany

Dominique Maugeais
RH Solutions

Dr Emmanuel Hanon
Viome (SAC Chair)

Phil Krause
World Health Organization

Rebecca Grais
Pasteur Network

Peter Smith
London School of Hygiene & Tropical Medicine

Gary Nabel
Modex Therapeutics

George Gao
Chinese Center for Disease Control and Prevention/ Institute of Microbiology, CAS

Inger Damon
Centers for Disease Control and Prevention USA/ Emory University

Stanley Plotkin
Emeritus Professor, University of Pennsylvania, USA

Sani Aliyu
Cambridge University Hospitals Foundation Trust

Josie Golding
Wellcome

Ken J. Ishii
International Vaccine Design Center, The Institute of Medical Science, The University of Tokyo

Kent Kester
IAVI

Rino Rappuoli
Fondazione Biotecnopolo di Siena

V. Krishna Mohan
Bharat Biotech, India

Laura Palomares
Instituto de Biotecnología, Universidad Nacional Autónoma de México (UNAM) (SAC Vice Chair)

Linfa Wang
Duke-NUS Medical School, Singapore

Vineeta Bal
Indian Institute of Science Education a Research, Pune, India

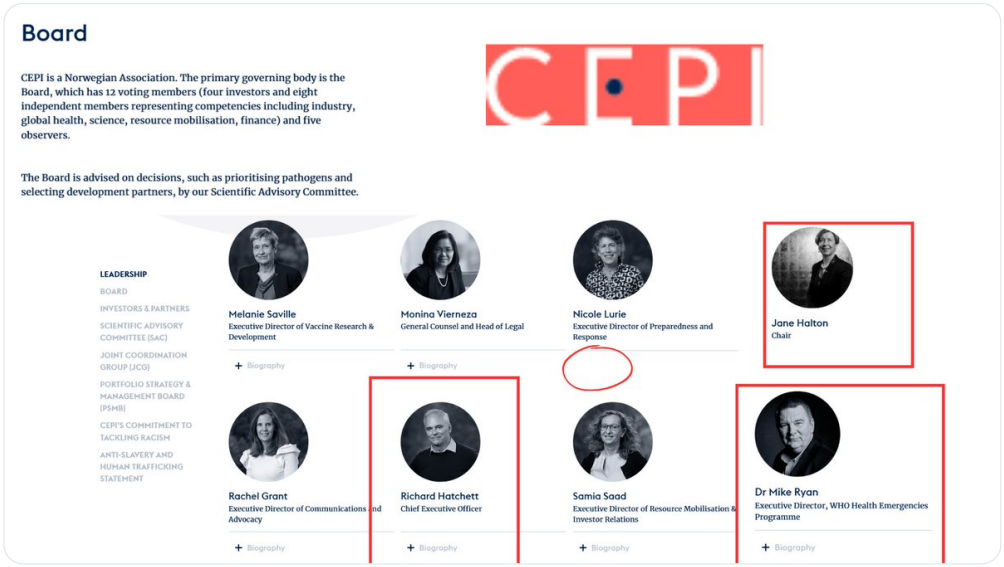
Stephen Thomas
SUNY Upstate Medical University, USA

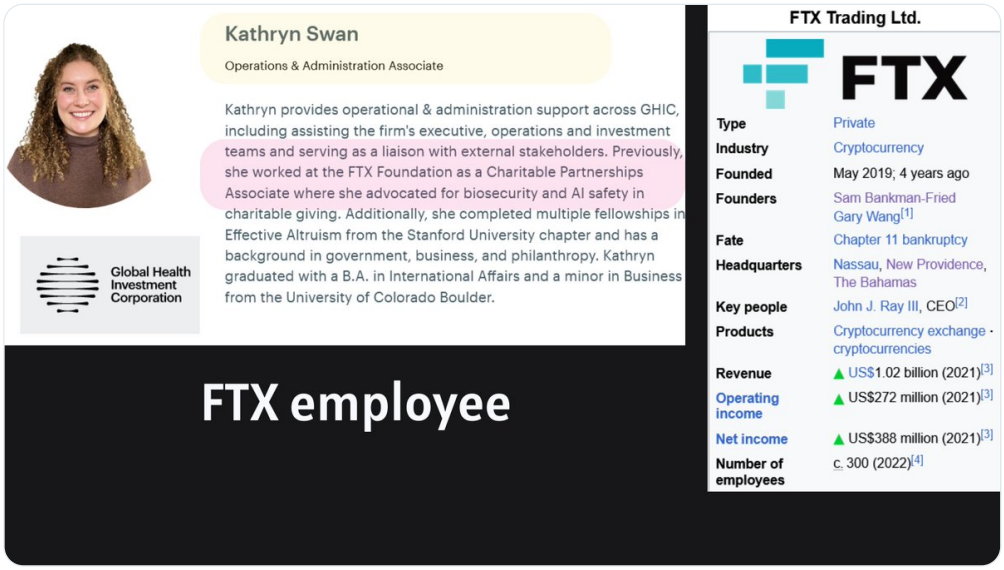
Luciana Borio
Arch Venture Partners

Mahmudur Rahman
GHD|EMPHNET

Marc Lipsitch
Harvard T.H. Chan School of Public Health USA

Vaseeharan Sathiyamoorthy
World Health Organization





7🧵CEPI's Joint Coordination Group includes; the European Medicines Agency, GAVI, UNICEF, FDA, WHO, & World Bank. CEPIs Scientific Advisory Committee which includes; Christain Drosten, China's CDC director George Gao, Stanley Plotkin [wrote the literal book on "Vaccines,"

CEPI

Scientific Advisory Committee (SAC)

The Scientific Advisory Committee is an independent body within the CEPI governing structure that provides world-class scientific support, advice, and guidance to CEPI staff and the CEPI Board in responding to the current COVID-19 pandemic.

They also deliver guidance and challenge towards CEPI's US$3.5bn plan to mitigate or even dramatically reduce the threat of future pandemics and epidemics. Final decision-making about the issues addressed by the committee rests with CEPI staff or the Board.

CEPI Joint Coordination Group

The current members of the Joint Coordination Group include:

- The African Vaccine Regulatory Forum (AVAREF)
- **Developing Countries Vaccine Manufacturers Network (DCVMN) member**
- **European Medicines Agency (EMA)**
- FIND, the global alliance for diagnostics
- **Gavi, the Vaccines Alliance**
- The Global Fund
- International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) member
- International Federation of Red Cross and Red Crescent Societies (IFRC)
- **Médecins Sans Frontières (MSF)**
- **UNICEF**
- **US Food and Drug Administration (FDA)**
- **Wellcome Trust**
- **World Bank**
- **World Health Organization (WHO)**

CEPI

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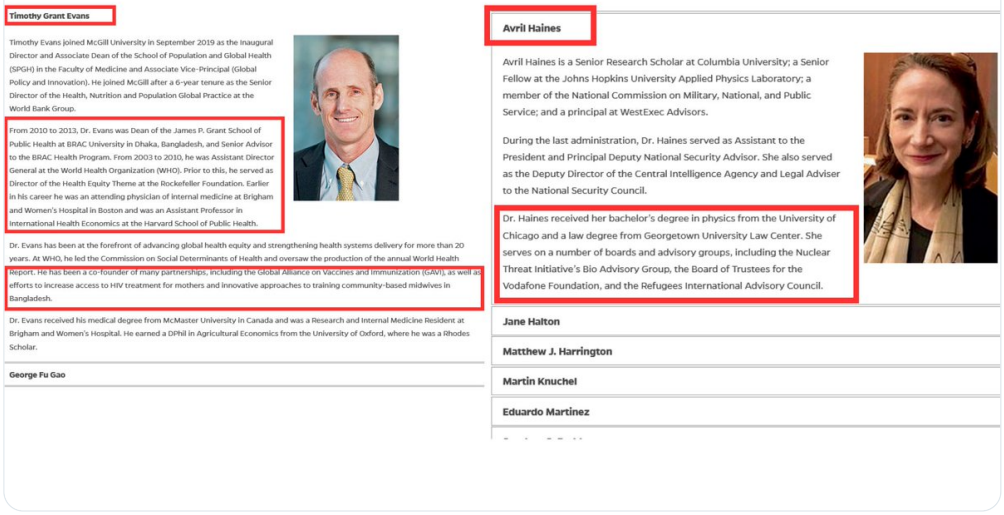
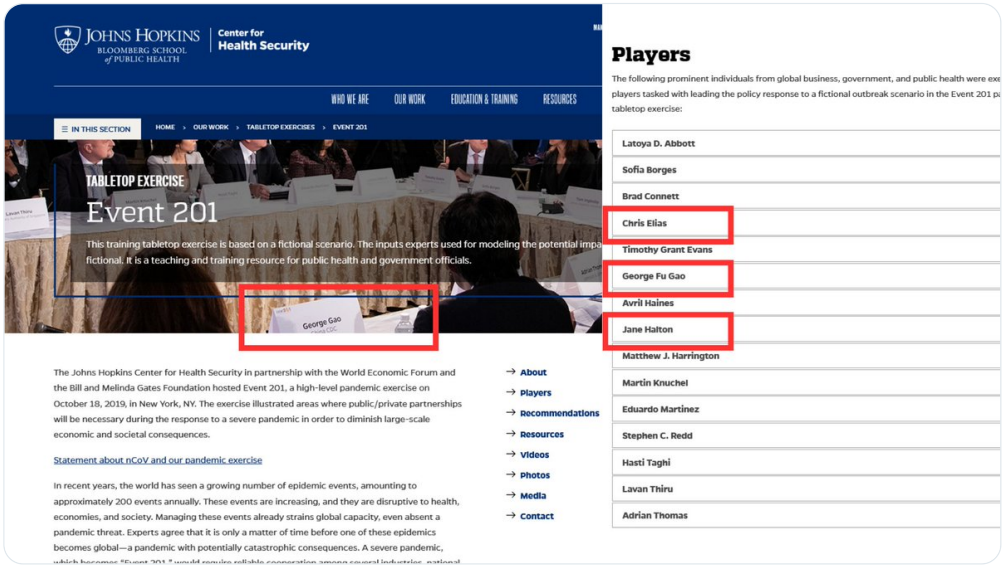
CEPI



8.🧵 It is worth noting that George Gao, who is China's CDC Director who was one of only 15 "players" at Event 201 in Fall of 2019 [hosted by WEF, BMGF, and Johns Hopkins] & is a two time board member for the Global Health Preparedness Monitoring Board is also CEPI.



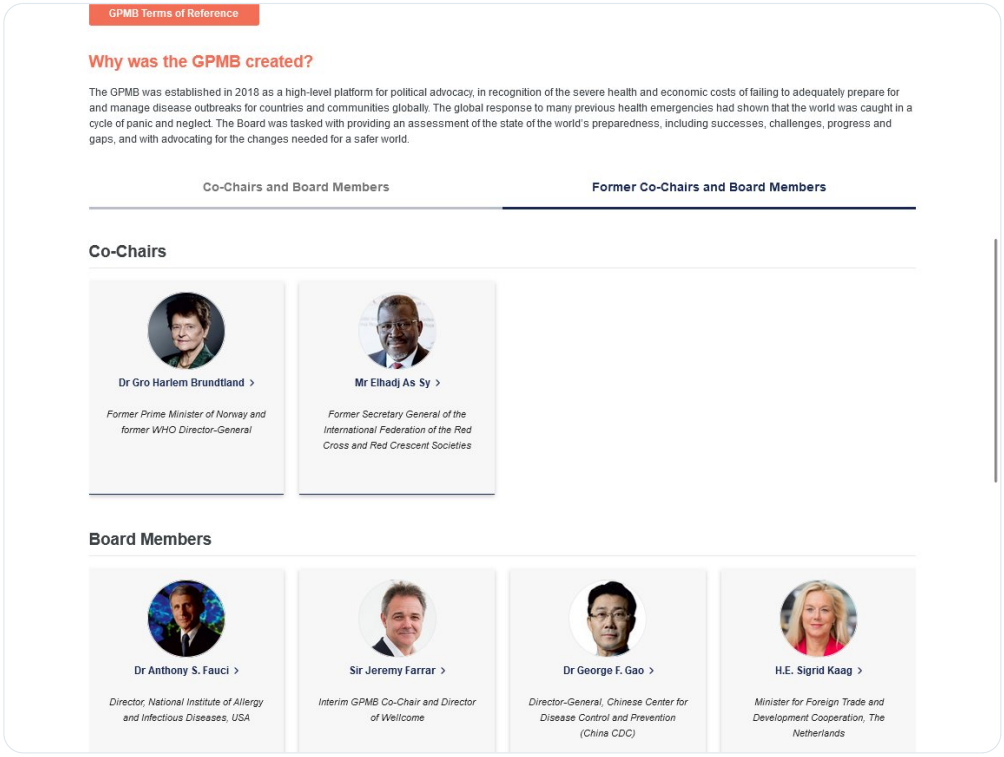
George Fu Gao

Professor George F. Gao is the Director-General, Chinese Center for Disease Control and Prevention; a Professor in the Institute of Microbiology, Chinese Academy of Sciences; President of the Chinese Society of Biotechnology; and President of the Asian Federation of Biotechnology (AFOB).

Dr. Gao obtained his DPhil degree from Oxford University, UK, and did his postdoc work in both Oxford University and Harvard University, with a brief stay in Calgary University. His research interests include enveloped viruses and molecular immunology. His group research is mainly focused on the enveloped virus entry and release, especially influenza virus interspecies transmission (host jump), structure-based drug-design, and structural immunology. He is also interested in virus ecology, especially the relationship between influenza virus and migratory birds or live poultry markets and the bat-derived virus ecology and molecular biology.

Dr. Gao has published more than 450 refereed papers and 10 books or book chapters, and he has applied for and obtained more than 25 UK, US, and Chinese patents. His research has recently expanded to public health policy and global health strategy. He led the China CDC team from September to November 2014 to work in Sierra Leone in the fight against Ebola.

Dr. Gao is a member (academician) of the Chinese Academy of Sciences, a fellow of the Third World Academy of Sciences (also known as the World Academy of Sciences), a fellow of the American Academy of Microbiology, and an associate member of EMBO. He is a recipient of several national and international awards, including the TWAS Medical Prize (2012), the Nikkei Asian Prize (2014), and the HLHL S&T Advancement Award (2015).



9🧵Two other JCG members at CEPI are Linfa Wang, a fellow bat expert w/ Shi Zeng Li. Wang is a UC Davis grad. The other is Luciana Borio; CFR member, Johns Hopkins Grad, & the CIA's venture fund, In-Q-Tel's, VP & inspiration for Resilience Inc/Moderna https://t.co/gSppzWKKtf

Destiny Rezendes ✓
@dezzie_rezzie · **Follow**

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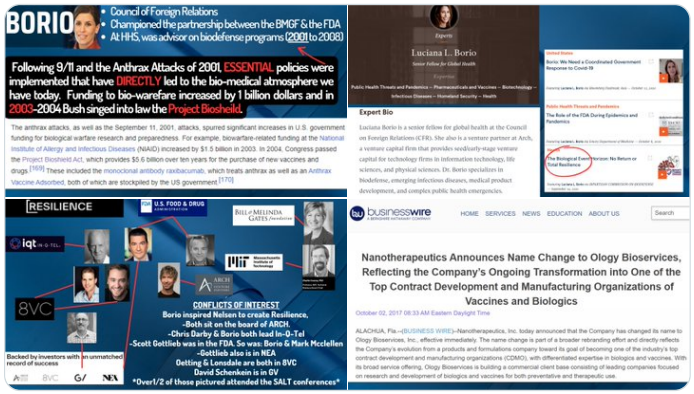
Resilience has acquired an insane $1.9 billion from just 4 funding rounds & in as little as 25months! How is that possible? Other than the gains made in acquisitions, Resilience itself was practically handed $800 million at its inception. Why? Luciana Borio...



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Linfa Wang

This biologist helped trace SARS to bats. Now, he's working to uncover the origins of COVID-19

Linfa Wang's innovative new assay could help reveal when and where the virus spilled over to humans

30 SEP 2020 • BY KAI KUPFERSCHMIDT

RS COMMENTARY JOURNALS | COVID-19 Science

Wang, who heads the Emerging Infectious Diseases Program at Duke-NUS Medical School in Singapore, immediately got to work developing a new assay that can detect antibodies against SARS-CoV-2 in blood samples—an indication of prior infection. The tool could help untangle how the pandemic began. So far, the evidence is that the virus originated in bats, animals Wang has long argued are uniquely suited to harboring viruses that pose a danger to humans. Now, he hopes his assay can help trace the path of the virus to humans and pinpoint when and where it first spilled over.

The work is a natural next chapter for Wang, who has been tracking viruses from bats to humans for more than 2 decades. Marion Koopmans, a virologist at Erasmus Medical Center, credits him for essentially launching the field of bat immunology and developing the tools to pursue it. "He has made a heroic effort to establish a very challenging research line, which needed to start from scratch," she says.

10🧵I've covered Borio and Linfa Wang in the past & their involvement cannot be understated. What's interesting is to see Borio in multiple articles in early 2020 in NEMJ, & JAMA that were co-authored by Jesse Goodman,a Georgetown univ grad & husband to Nicole Luire.

VIEWPOINT

Finding Effective Treatments for COVID-19

Scientific Integrity and Public Confidence in a Time of Crisis

Jesse L. Goodman, MD, MPH, Georgetown University, Washington, DC.

Luciana Borio, MD In-Q-Tel, Arlington County, Virginia.

Everyone wants new treatments and vaccines to address the devastation of coronavirus disease 2019 (COVID-19). But, currently, under intense pressure and based on hope and limited data from poorly conducted clinical trials and observational data, many clinicians are embarking on ill-advised and uncontrolled human experimentation with unproven treatments.[1] This approach cannot provide answers about what treatments are effective, and it poses undue risk to patients. In this light, decisions to seek and invoke Emergency Use Authorization (EUA) authorities from the US Food and Drug Administration (FDA), such as the recent EUA for chloroquine and hydroxychloroquine,[2] which will further increase use of these drugs for treating individuals with COVID-19, are noteworthy and deserve careful attention. Not only are there potential negative consequences from uncontrolled use of these drugs based on currently unconvincing data but, equally concerning, the integrity of governmental decision-making is increasingly coming under pressure, risking harm to both patients and to the public confidence needed to respond effectively to this pandemic.

In 2014, Ebola virus disease, then believed to be fatal to most infected individuals, was widespread in West Africa. Early doses of "secret serum," the triple monoclonal antibody combination (ZMapp), were given to 2 US citizens. Both survived, generating intense global pressure to use this product and other unproven treatments. At the time, it was argued[3] that even promising therapies most often prove ineffective or harmful and that, even in an emergency, the fastest route to learning whether experimental products work was with randomized clinical trials (RCTs). At the same time, it was noted that, provided adequate supplies, access for patients who could not enroll in clinical trials could be facilitated through FDA "compassionate use" (or "expanded access") provisions. Such provisions, unlike EUA, require consent and provide enhanced clarity to physicians and patients that the product is experimental and not necessarily endorsed by the government.

> As learned from the Ebola outbreak, mortality can be reduced through identifying best practices.

However, there was extreme resistance to conducting RCTs, and by the time a study that compared the monoclonal antibody combination therapy with standard care was underway, the epidemic was waning and the trial terminated before it could reach definitive conclusions. It took 4 years and another outbreak to learn that any potential benefit afforded by this triple antibody product was less than that of 2 similar treatments. Furthermore, because of the deficit of RCTs, it is still not known whether other experimental Ebola treatments are of value or may be injurious. As a result of these experiences, a consensus emerged that sound research can and should be done during emergencies and that RCTs are the most ethical and reliable approach to quickly identify effective treatments and ensure that the most people benefit.[4]

In this context, the recent issuance of the chloroquine/hydroxychloroquine EUA, in the midst of political pressure and with scant and conflicting supporting evidence, should be of serious concern. Although everyone hopes these drugs will be found to work, the weakness of currently existing efficacy data and safety concerns are significant.[5,6] Furthermore, growing enthusiasm about the drugs has resulted in unintended consequences, including anecdotal reports of fatal ingestions as well as hoarding that puts patients who need the drugs for proven indications at risk. Resulting shortages also risk promoting production and use of substandard or counterfeit substitutes.

Why the concern about EUAs? An EUA is intended to allow use of select experimental products or of approved products for unproven indications with exceptions to FDA requirements that may not be feasible to meet during some emergencies (eg, good manufacturing practices, institutional review boards, written informed consent). EUA issuance requires the FDA's scientific review, an independent process of high integrity, to conclude that it is reasonable to believe that "the known and potential benefits of the product, when used to diagnose, prevent, or treat the identified disease or condition, outweigh the known and potential risks of the product."[4] Although this standard is short of requirements for full drug or biologic approvals, it still depends on careful weighing of available evidence and represents a de facto government judgment in support of a specific use in a specific emergency. Although unintended, it is not infrequent to see an EUA portrayed as akin to an FDA approval, including now for chloroquine/hydroxychloroquine.[7]

EUAs that have been requested and granted in the past, such as during the anthrax attacks of 2001 and the 2009 pandemic influenza A(H1N1), have all been underpinned by substantive evidence supporting the standard of known and potential benefits being likely to exceed risks, particularly as compared with the recent chloroquine/hydroxychloroquine EUA. For example, oseltamivir, a drug of known safety and

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jama.com JAMA Published online April 16, 2020 E1

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In-Q-Tel, Arlington County, Virginia.

VIEWPOINT

The US Regulatory System and COVID-19 Vaccines
The Importance of a Strong and Capable FDA

Joshua M. Sharfstein, MD
Bloomberg School of Public Health, Johns Hopkins University, Baltimore, Maryland.

Jesse L. Goodman, MD, MPH
Medicine and Infectious Diseases, Georgetown University, Washington, DC.

Luciana Borio, MD
In-Q-Tel, Arlington County, Virginia.

For many in public health and medicine, the coronavirus disease 2019 (COVID-19) pandemic in the US has been a frustrating journey from one disappointment to the next: late access to testing, insufficient staff and inadequate funding for contact tracing, jumbled communications, and, at the end of 2020, a chaotic launch of vaccination efforts. But in one area, from the beginning of the pandemic to the present, the US has excelled: facilitating the rapid development of COVID-19 vaccines. Much of the credit has justifiably gone to the scientists who adopted and created the technology, to the companies that made the vaccines, to the participants who volunteered for clinical trials, to the National Institutes of Health, and to Operation Warp Speed, which funded several candidate vaccines, minimizing financial risk for the companies. A less recognized partner in this effort—but no less essential to its success—is the US Food and Drug Administration (FDA).

In early spring 2020, the quest to develop vaccines was described as a competition between nations, with anticipation that countries first to vaccinate would gain a geopolitical advantage.[1] As the virus spread from country to country, governments had to decide among dozens of competing technologies, many with a plausible argument for success. Biomedical researchers from across the world joined the effort to develop a vaccine. Global efforts to develop vaccines provided early funding, and national leaders planned to spend whatever resources would be necessary.

US success and global leadership will continue to depend on innovative science, sufficient resources, and a strong and capable FDA.

From the start of this effort, a pivotal question was how to define success. What evidence would be required to assess risks and benefits and to know whether a vaccine is ready for broad use?

The FDA approached these questions by engaging colleagues at the National Institutes of Health, working with scientists at the companies, hearing from academic experts, and then, most importantly, by relying on the experience of the agency's own scientists in the Office of Vaccine Research and Review, many of whom have spent their careers overseeing and assessing vaccine development. Early questions included what toxicology studies were needed, how to assess safety and immune response in the early human trials, and how to select a dosing regimen.

The FDA then had to decide on the types and amounts of scientific evidence needed to determine that a vaccine candidate is safe and effective for use by millions of people. The agency came under substantial pressure to consider authorizing vaccines based on immunogenicity data that measure a vaccine's ability to induce an immune response. However, given limited scientific understanding of what constitutes protective immunity to severe acute respiratory syndrome coronavirus 2, the agency, with support from many leading scientists, insisted on meaningful clinical outcomes.[2] In a widely read guidance released in June 2020, the agency said that for licensure, a vaccine would need to achieve at least a 50% reduction in COVID-19 disease, with confidence intervals that excluded less than a 30% reduction.[3] This guidance required companies to establish safety and efficacy of their vaccines by conducting large, diverse, controlled phase 3 clinical trials involving tens of thousands of patients. The FDA scientific staff then worked closely with the World Health Organization in efforts to promote high standards globally.

Not all nations waited for clinical results before using vaccines widely. In August 2020, Russia approved its vaccine and reportedly had administered it to more than 2 million people before completing trials or releasing data about its safety and efficacy. Neither naming their vaccine Sputnik nor declaring the race over answered serious questions in the scientific or clinical community. In September, China began vaccinating thousands of people, including employees at state-owned businesses, government officials, and company executives, also before clinical trials were completed.

In October 2020, the FDA built on its earlier guidance on standards for licensure to explain what data would be needed to support the potential interim step of emergency use authorization.[4] The agency's scientists and, ultimately, Commissioner Stephen Hahn resisted White House efforts to prevent the issuance of this guidance and to establish a low bar, such as relying only on very early and interim data with minimal safety information. Instead, the agency required a minimum number of clinical cases, including serious disease, to occur in the clinical trial cohort before reaching an efficacy end point, and required a median of 2 months of safety follow-up, as well as submission of a full data set for its own analysis of the data.

In November, Pfizer-BioNTech and then Moderna announced positive results of their clinical trials. The FDA quickly conducted its own analyses of the companies' raw data, confirming high efficacy and a reassuring safety

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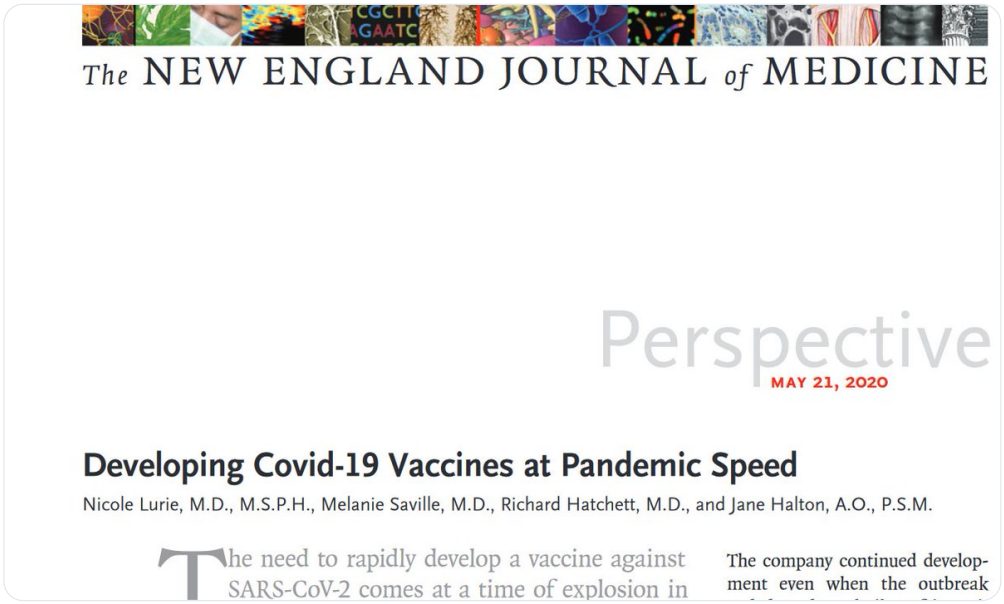


The NEW ENGLAND JOURNAL of MEDICINE

Perspective

MAY 21, 2020

Developing Covid-19 Vaccines at Pandemic Speed

Nicole Lurie, M.D., M.S.P.H., Melanie Saville, M.D., Richard Hatchett, M.D., and Jane Halton, A.O., P.S.M.

The need to rapidly develop a vaccine against SARS-CoV-2 comes at a time of explosion in

The company continued development even when the outbreak

11🧵Nicole Lurie sits on the board for CEPI, although her bio seems to be missing from their page. Lurie was the Assistant Secretary for Preparedness and Response under the Obama admin, RAND member, who was responsible for the gov't response to the Flint water crisis.

Nicole Lurie

Add language

Article Talk Read Edit View history Tod

From Wikipedia, the free encyclopedia

You have a new message (last change).

Nicole Lurie is an American physician, professor of medicine, and public health official. During the administration of President Barack Obama, she was Assistant Secretary for Preparedness and Response (ASPR) at the United States Department of Health and Human Services (HHS) from 2009 through the end of the president's second term. The mission of the Office of the Assistant Secretary for Preparedness and Response is to "lead the nation in preventing, responding to and recovering from the adverse health effects of public health emergencies and disasters, ranging from hurricanes to bioterrorism."[1]

Education [edit]

Lurie received her bachelor's degree from the University of Pennsylvania and her M.D. from the University of Pennsylvania Medical School in 1979.[1][2] Lurie received her Master of Science in Public Health from the University of California, Los Angeles (UCLA), where she also completed her medical residency.[1] Lurie was a Robert Wood Johnson Foundation Clinical Scholar at UCLA.[1]

Nicole Lurie

Personal details

Education University of Pennsylvania (BS, MD)
(University of California, Los

In 1998, Lurie took leave from her position in Minnesota to become Principal Deputy Assistant Secretary for Health in the U.S. Department of Health and Human Services, holding this position until 2001. In this role, Lurie worked on the Healthy People 2010 initiative and initiative to reduce health disparities, as well as pandemic influenza planning.[2]

After leaving HHS, Lurie became senior natural scientist and the Paul O'Neill Alcoa Professor of Health Policy at the Arlington, Virginia-based Rand Corporation, a think tank.[2][3] Lurie directed the organization's Center for Population Health and Health Disparities and oversaw its work on public health and preparedness.[2] Lurie testified before the Subcommittee on Bioterrorism and Public Health Preparedness of the Senate Committee on Health, Education, Labor and Pensions in March 2006, explaining that "her work included evaluating public health preparedness in California and Georgia; conducting 32 tabletop exercises on hypothetical crises caused by smallpox, anthrax, botulism, plague, and pandemic influenza; and interviewing officials from 44 communities in 17 states."[2][4]

In July 2009, Lurie returned to HHS as Assistant Secretary for Preparedness and Response at the Department of Health and Human Services. In that position, Lurie oversaw the federal public health response to various health crises, including Hurricane Sandy and the Boston Marathon bombing.[2] Lurie is also a rear admiral of the U.S. Public Health Service.[1] Lurie was also appointed to oversee the federal response to the Flint water crisis.[5]

While serving as assistant secretary at HHS, Lurie also practiced medicine at the Bread for the City clinic in Washington, D.C.[1][2]

Personal life [edit]

Lurie is married to Dr. Jesse L. Goodman, a physician and now the chief scientist at the Food and Drug Administration; the two met while at the University of Pennsylvania. They have three sons.[2]

12 🧵 Lurie's husband, Jesse Goodman- former CBER director, & FDA chief Scientist, on the board for GSK, the United States Pharmacopeia [USP] which sets standards for health care products in the U.S recognized as official by the federal government and are enforceable by the FDA.

What is the focus of Nicole Lurie's work at CEPI

Quick Search

Nicole Lurie, MD, MSPH | AME – Academic Medica... · academicmedical... · 1

Nicole Lurie – CEPI · cepi · 2

Nicole Lurie, MD, MSPH | The Commonwealth Fun... · harvard · 3

CEPI appoints former Assistant Secretary for... · homelandprepne... · 4

Former Assistant Secretary for... · cepi · 5

Nicole Lurie Named Penn LDI Distinguished Health... · upenn · 6

Answer

Nicole Lurie's work at CEPI (Coalition for Epidemic Preparedness Innovations) focuses on preparedness and response to public health emergencies, including the development of vaccines to stop future epidemics [1][2][5]. As the Executive Director for Preparedness and Response at CEPI and Director of CEPI-US, Lurie has been guiding CEPI's emergency response efforts since 2017, including its COVID-19 response [4]. Prior to COVID-19, CEPI's work focused on developing vaccines against Ebola [5].

3. **Assistant Secretary for Preparedness and Response (ASPR)**: During the administration of President Barack Obama, Lurie served as the Assistant Secretary fo Preparedness and Response at the United States Department of Health and Human Services (HHS) from 2009 through the end of the president's second term [1]. In this role, she was responsible for leading the nation's efforts to prepare for and respond t public health emergencies.
4. **CEPI**: Lurie was appointed as the US Director at CEPI (Coalition for Epidemic Preparedness Innovations), a global partnership to develop vaccines to stop future epidemics [3]. She also serves as the Executive Director for Preparedness and Response at CEPI and Director of CEPI-US [2].
5. **Penn LDI Distinguished Health Policy Fellow**: Lurie was named a Penn LDI Distinguished Health Policy Fellow in 2017 [6]. This fellowship recognizes her expertise ir health policy.

Nicole Lurie is connected to several organizations in her career. Here are the organizations she is connected to:

1. **World Bank**: Nicole Lurie is currently a consultant to the World Bank [1]. Her role in this capacity is not specified in the search results.
2. **Coalition for Epidemic Preparedness Initiatives (CEPI)**: Lurie is connected to CEPI and holds multiple roles within the organization. She is the Executive Director for Preparedness and Response at CEPI and also serves as the Director of CEPI-US [3][5].
3. **United States Department of Health and Human Services (HHS)**: Lurie served as the Assistant Secretary for Preparedness and Response (ASPR) at HHS during the administration of President Barack Obama [2][4]. In this role, she provided leadership in preventing, responding to, and recovering from the adverse health effects of public health emergencies and disasters [1].
4. **Bread for the City clinic**: While serving as the assistant secretary at HHS, Lurie also practiced medicine at the Bread for the City clinic in Washington, D.C. [2].
5. **Society of General Internal Medicine**: Lurie was elected to the council of the Society of General Internal Medicine in 1987 and served as its president from 1997 to 1998 [2].
6. **Institute of Medicine**: Lurie is a member of the Institute of Medicine [2]. The Institute of Medicine is now known as the National Academy of Medicine.

These organizations highlight Lurie's involvement in public health, emergency preparedness, and healthcare policy at both national and international levels.

U.S. Pharmacopeia (USP)

Jesse L. Goodman, M.D., M.P.H.

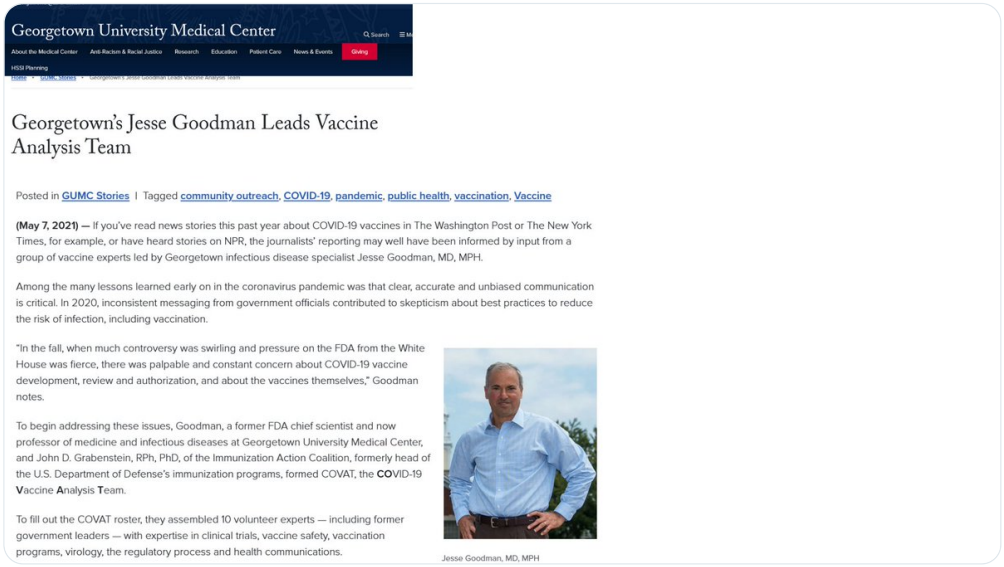
Medical Sciences Trustee

Having served as President of the USP Convention during the 2015-2020 cycle, Dr. Jesse Goodman will help guide USP as it begins its third century of promoting and protecting public health. In his role as Medical Sciences Trustee on USP's board, Dr. Goodman will apply his knowledge of USP along with his personal and professional experience as the organization rises to the challenges of the global supply chain and helping to ensure ongoing access to quality medicines for people around the world.

His day-to-day experiences as a practicing clinician coupled with the knowledge that he gained during years with FDA have given Dr. Goodman an appreciation for the need for balanced and collaborative approaches to regulations and what that could do to keep our drug and food supply as safe and effective as possible.

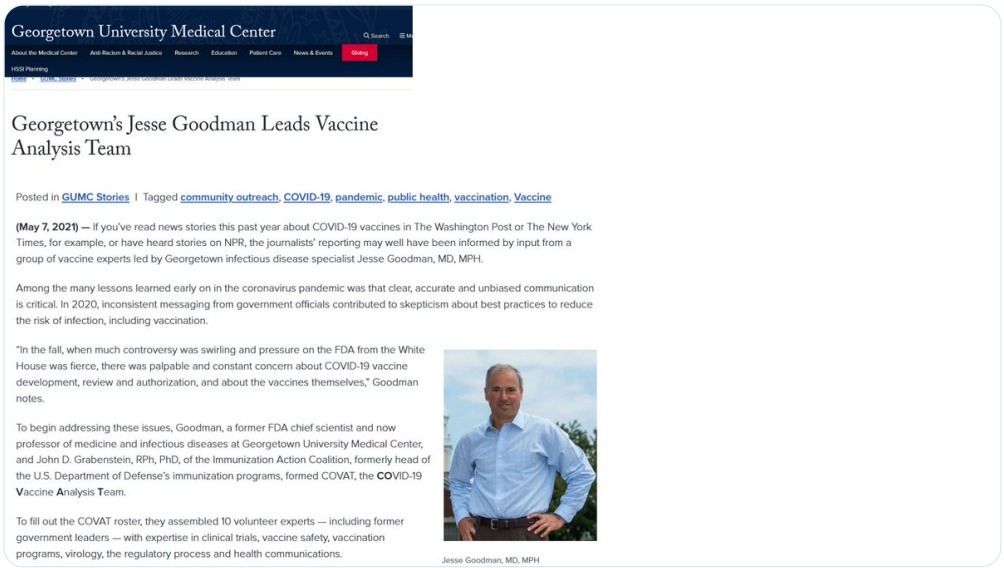
Dr. Goodman is the Director of the Center on Medical Product Access, Safety and Stewardship and attending physician at Georgetown University and DC Veterans Administration Hospitals. Until 2014, Dr. Goodman was FDA's Chief Scientist, leading crosscutting scientific efforts, including public health preparedness and medical countermeasures. Prior to that, Dr. Goodman directed FDA's Center for Biologics Evaluation and Research, supporting innovative regulatory approaches to vaccines and other biologics and spearheading unique public–private efforts to address public health challenges. As Senior Advisor to the Commissioner, he initiated the first U.S. Task Force on Antimicrobial Resistance. Having served on the World Health Organization's Ebola Vaccine Working Group, Dr. Goodman helped develop the Global Vaccine Action Plan. He is currently on the Centers for Disease Control and Prevention's Board of Scientific Counselors (Infectious Diseases).

A Harvard graduate, Dr. Goodman received his M.D. from Albert Einstein College of Medicine and completed postdoctoral training at the University of Pennsylvania and UCLA, where he was Chief Resident. He has been elected to the Institute of Medicine of the National Academy of Sciences.



13 🧵 Goodman has also been on the boards for WHO, CDC, NIH, & like his wife, Lurie, he too sat on the board for CEPI. Goodman and CIA darling Borio authored many narrative based articles in early 2020 but why? Turns out they share roles together at COVAT

14 🧵 COVAT= COVID-19 Vaccine Analysis Team, ran by Georgetown University & it began September 25th 2020. Alongside Borio & Goodman are influential names like, Paul Offit, Walter Orenstein, and Vaxophile Peter Hotez-all to give pro-vaccine guidance.



"Our experts include former FDA, CDC, White House, DOD and HHS scientific leaders, leading academic experts from around the country, and media and public health experts," Goodman says. "We've all worked together in some capacity over the years."

COVAT's blue-ribbon panel of experts include a former commissioner of health for New York City, the former directors of both the Office of Vaccines Research and Review and the Division of Epidemiology at FDA, the former director for medical and biodefense preparedness at the National Security Council, the previous director of the National Vaccine Program Office at HHS, the former communications director for the CDC, and two leading academic vaccine developers.

View a List of COVAT Members

Mary Bassett, MD, MPH, François-Xavier Bagnoud Professor of the Practice of Health and Human Rights, director of the François-Xavier Bagnoud Center for Health and Human Rights; former commissioner of health for New York City

Norman Baylor, PhD, president and CEO, Biologics Consulting; former director o FDA's Office of Vaccines Research and Review

Luciana Borio, MD, vice president In-Q-Tel; former director for Medical and Biodefense Preparedness at the National Security Council; former FDA acting chief scientist

M. Miles Braun, MD, MPH, adjunct professor, Georgetown University School of Medicine; former director of FDA's Division of Epidemiology

Bruce Gellin, MD, MPH, president, Global Immunization, Sabin Vaccine Institute; former deputy assistant secretary for health and director of the National Vaccine Program Office, U.S. Department of Health and Human Services

Jesse L. Goodman, MD, MPH, COVAT chair; professor of medicine and infectious diseases, Georgetown University; former FDA chief scientist and former director of the FDA Center for Biologics Evaluation and Research

John D. Grabenstein, RPh, PhD, COVAT co-chair; colonel, U.S. Army (retired); editor for Immunization Action Coalition; general manager of Vaccine Dynamics; former global executive director of medical affairs, Merck Vaccines; former senior scientist and director for U.S. Department of Defense military immunization program

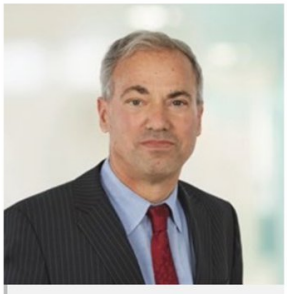
Peter Hotez, MD, PhD, dean, National School of Tropical Medicine; professor of pediatrics and molecular virology & microbiology, Baylor College of Medicine; director, Texas Children's Hospital Center for Vaccine Development

Glen Nowak, PhD, strategic communications advisor to COVAT; director, Center for Health and Risk Communication, professor of advertising, University of Georgia; former director of media relations at CDC and communications director for CDC's National Immunization Program

Paul A. Offit, MD, director, Vaccine Education Center, professor of pediatrics, division of infectious diseases, Children's Hospital of Philadelphia; Hilleman Professor of Vaccinology, Perelman School of Medicine, University of Pennsylvania

Walter A. Orenstein, MD, professor of medicine, epidemiology, global health anc pediatrics, Emory University; associate director, Emory Vaccine Center; director, vaccine policy and development; former deputy director, Immunization Programs, Gates Foundation; former director, CDC National Immunization Program

Link: https://gumc.georgetown.edu/gumc-stories/georgetowns-jesse-goodman-leads-vaccine-analysis-team/#



Bio and Featured Works

Teaching

Grants, Awards, Honors, Patents

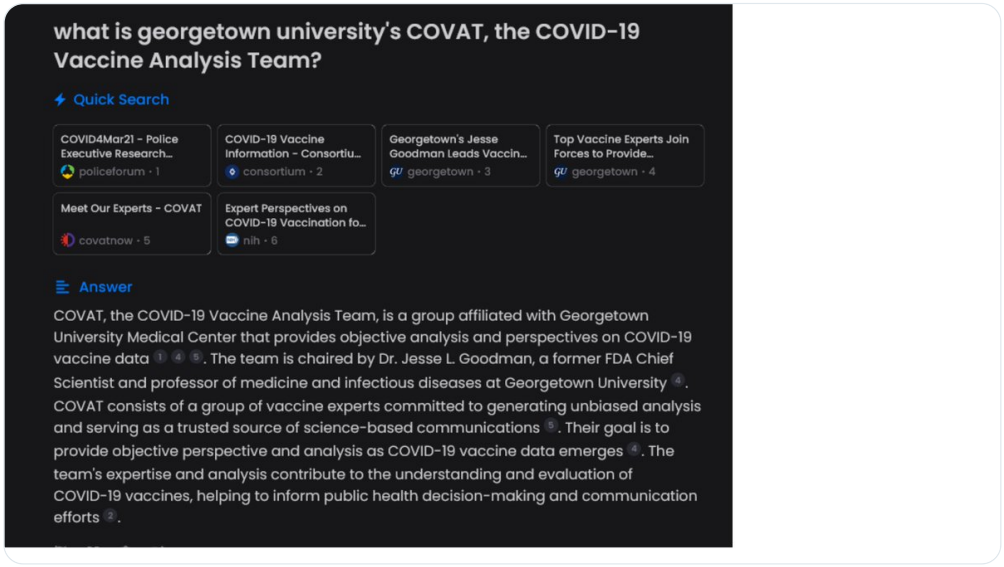
A graduate of Harvard, Dr. Goodman received his M.D. from the Albert Einstein College of Medicine and did residency and fellowship training in Medicine, Infectious Diseases and Oncology at the Hospital of the University of Pennsylvania and at the University of California in Los Angeles (UCLA), where he was also Chief Medical Resident. Prior to his government service, he was Professor of Medicine and Chief of Infectious Diseases at the University of Minnesota where his laboratory isolated and characterized *Anaplasma phagocytophilum*, the etiologic agent of granulocytic anaplasmosis, then a newly recognized tick-borne disease.

He has served on numerous Advisory Boards and Committees for organizations including the CDC, NIH, and WHO, and helped develop the R and D section of the Global Vaccine Action Plan. He previously served on the Scientific Advisory Board of the Coalition on Epidemic Preparedness Innovations (CEPI) and currently is a Member of CDC's Board of Scientific Counselors. In 2015, he was elected volunteer President and Board member of the United States Pharmacopeia, a non-profit standards setting organization working to advance safety and quality of medicines and foods globally. In 2016, he joined the Board of GSK, chairing its Science Committee, and in 2018 the Board of Intellia Therapeutics. He has been elected to the American Society for Clinical Investigation and to the National Academy (Institute) of Medicine of the National Academy of Sciences, where he is a longstanding member of its Forum on Microbial Threats.

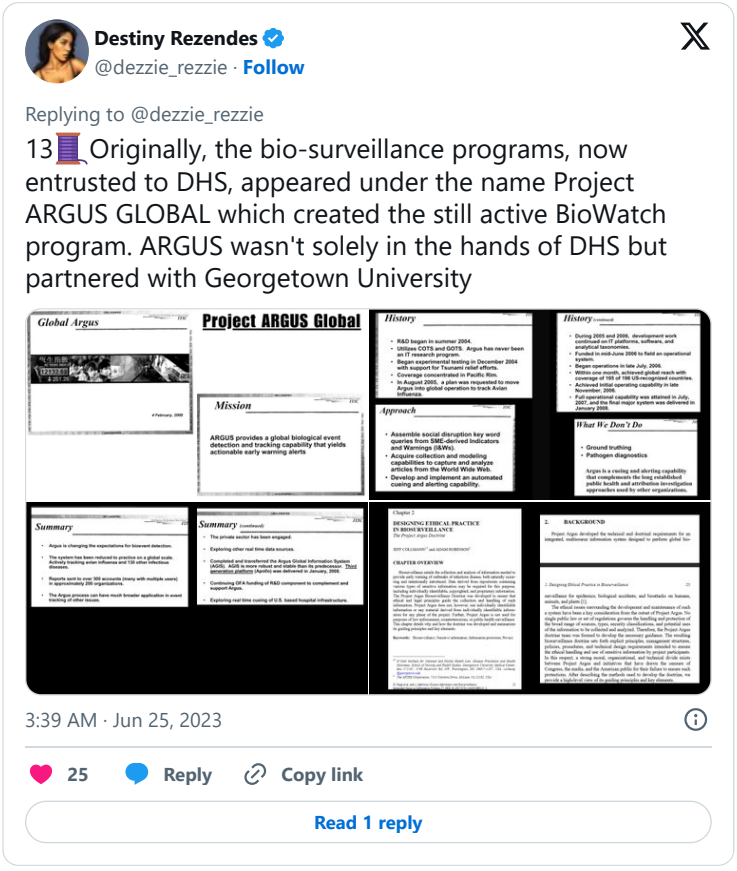
Language(s)

Spanish (Speak Read)

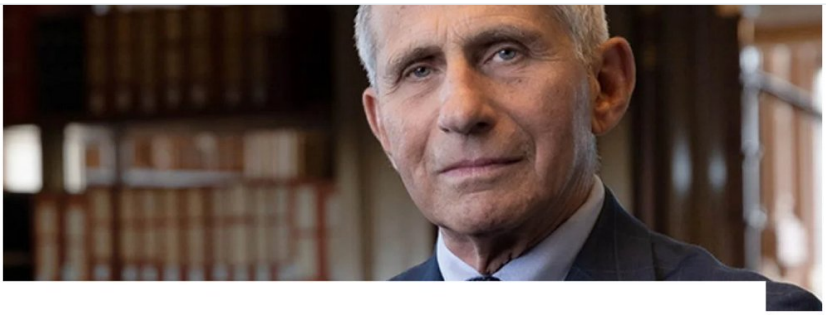
Link COVAT: https://www.policeforum.org/covid4mar21



15🧵In prior threads I have covered the alarming connection between Moderna's C19 jab and the CIA, namely Borio via Nat'l Resilience, as well as Georgetown's decades long health agendas.. https://t.co/U7rP8ixuke



16🧵As I've gone over before Georgetown Univ is one of the biggest purveyors of global health surveillance systems & often at the behest of the CIA/DoD. Not only is Goodman a professor, but so is EcoHealth's William Karesh, Katz, & Carlin, & as was recently announced Dr. Fauci.



University News

Dr. Anthony Fauci To Join Georgetown Faculty as Distinguished University Professor

June 26, 2023

After dedicating 54 years of his life to public service, Dr. Anthony Fauci has chosen Georgetown University to play a major role in the next phase of his career.

GEORGETOWN UNIVERSITY

Who We Are Campus & City

As a Distinguished University Professor at Georgetown, Fauci will participate in medical and graduate education and engage with students.

"I am delighted to join the Georgetown family, an institution steeped in clinical and academic excellence with an emphasis on the Jesuit tradition of public service," Fauci said. "This is a natural extension of my scientific, clinical and public health career, which was initially grounded from my high school and college days where I was exposed to intellectual rigor, integrity and service-mindedness of Jesuit institutions."

University News

5 Questions for Dr. Fauci on Why He Decided To Join Georgetown

How Jesuit Education Influenced Dr. Fauci

Fauci's Catholic upbringing and Jesuit education left an imprint on his career trajectory and approach to medicine and public service. He graduated from Regis High School in New York City in 1958 and the College of the Holy Cross in 1962 — two Jesuit institutions that cultivated intellectual rigor and service to others, he said.

Link: https://www.georgetown.edu/news/dr-anthony-fauci-to-join-georgetown-faculty-as-distinguished-university-professor/

CENTER for GLOBAL HEALTH SCIENCE & SECURITY

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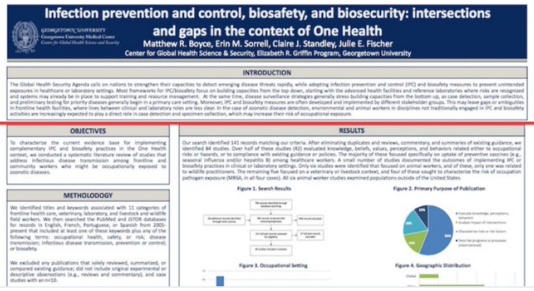
Biosafety Research

The Elizabeth R. Griffin Program focuses on strengthening the evidence base for implementing biosafety, biosecurity, and occupational health programs for the workers on the frontlines of laboratory research and health security.

Biosafety and One Health poster presented at the 15th International CDC Biosafety Symposium.



Infection prevention and control, biosafety, and biosecurity: intersections and gaps in the context of One Health

Matthew R. Boyce, Erin M. Sorrell, Claire J. Standley, Julie E. Fischer

Center for Global Health Science & Security, Elizabeth R. Griffin Program, Georgetown University

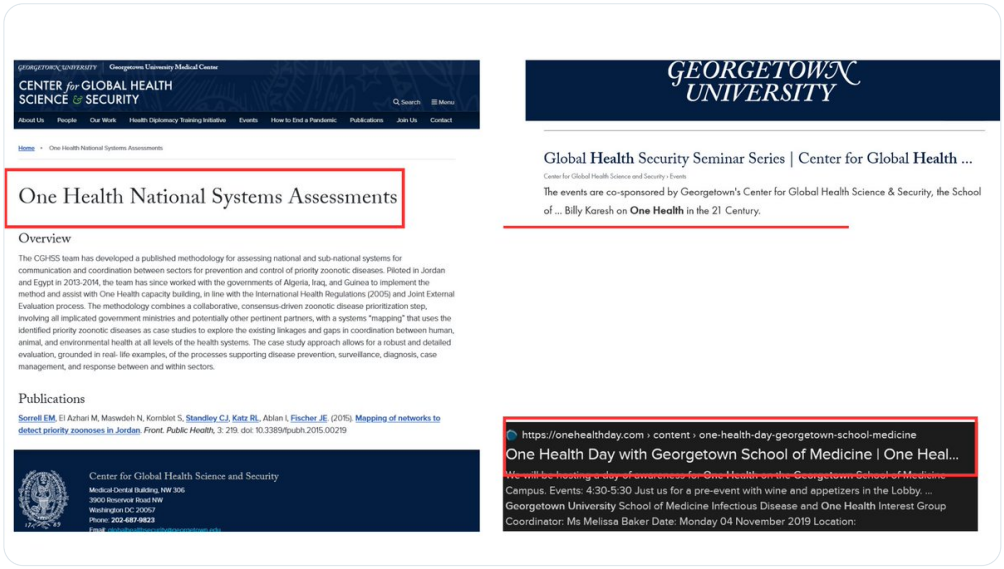
INTRODUCTION

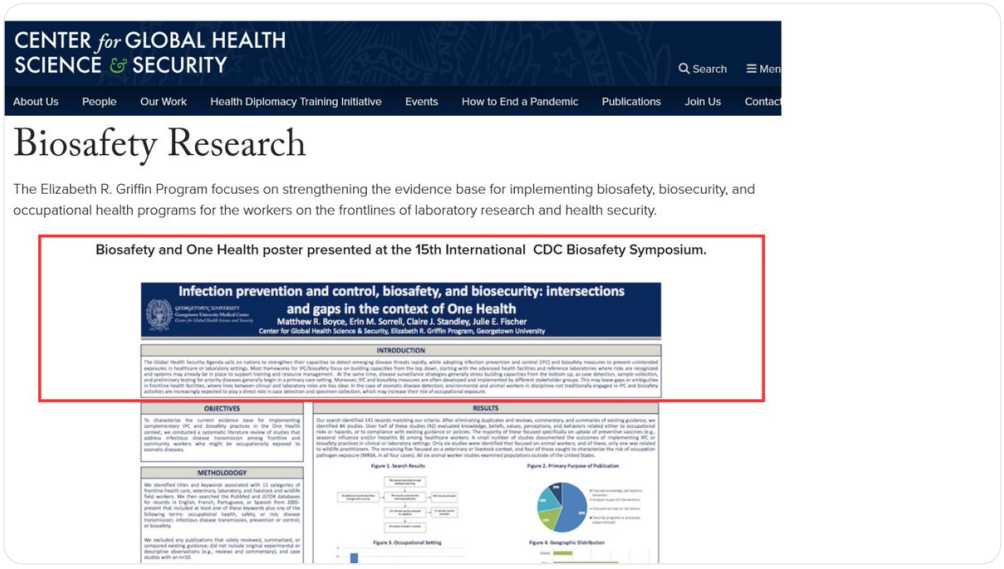
OBJECTIVES

METHODOLOGY

RESULTS

17🧵Not only is GU entrenched in all the aforementioned affiliations but Georgetown is a huge player in the "One Health" agenda. So much so that they convened the first International Global Health Security Conference (GHS 2019) making OneHealth a focus. https://t.co/IvwVbkbL6Z[ghs2019.com/index.php](ghs2019.com/index.php)





18🧵So why is this important? Because CEPI is pushing to 100 days to make vaccines agenda, which is being pushed into; EU, WHO, UN, & CDC. OneHealth is in the WHO treaty & IHR amendments and soon will be enacted. Both are EcoHealth Alliance & BMGF creations. Do YOU trust them?

link: https://apps.who.int/iris/bitstream/handle/10665/336838/PMC7652556.pdf?sequence=1

News

William Karesh: championing "One Health"

Preventing and responding to pandemics requires an integrated approach to human, animal and environmental health. William Karesh talks to Andréia Azevedo Soares.

2020

Q: How did you become interested in the interface between human and animal health?

A: You could say it started with the animals. I grew up outside a small city in coastal South Carolina where there was a lot of wildlife. I would find orphaned baby animals and raise them. That turned into a passion that stayed with me through my education in biology and veterinary medicine. As for the interface, I think it just seemed obvious to me that all these different biological organisms, including us, are interconnected and that it makes sense to look at them as an ensemble. In the past two hundred years or so, the development of different medical specializations has discouraged cross-disciplinary thinking

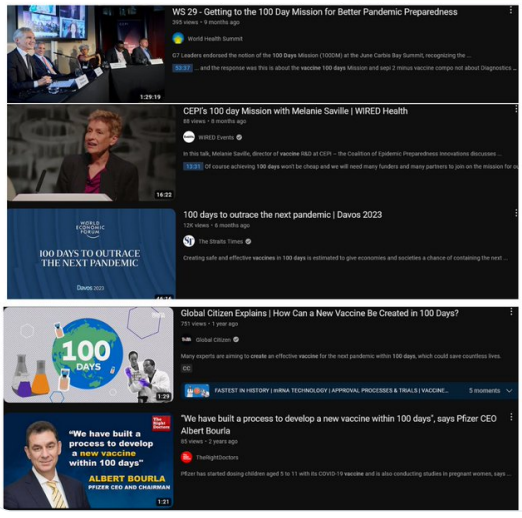
Courtesy of William Karesh

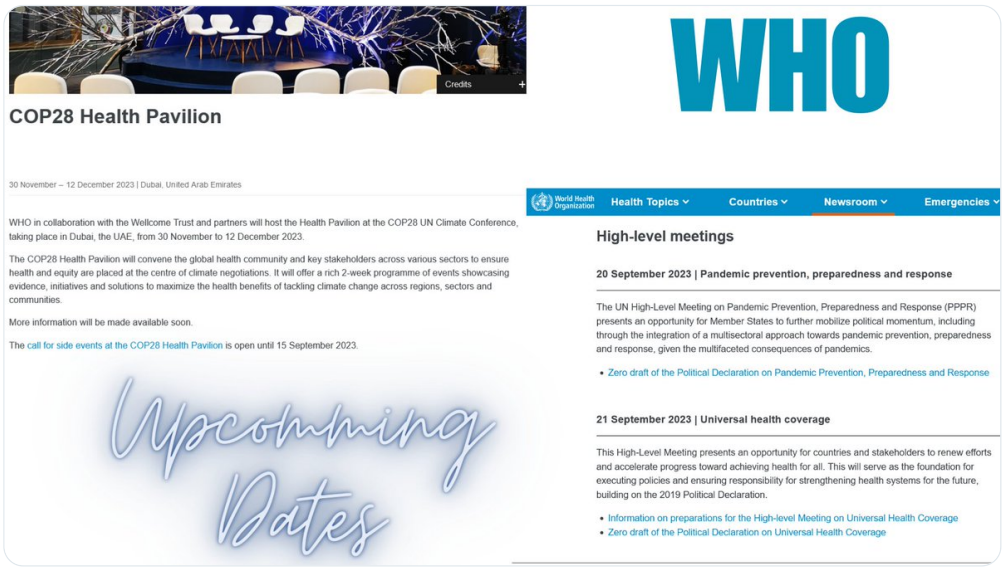
William Karesh

William B Karesh is an internationally recognized authority on "One Health", an integrated approach to animal, human and environmental health. He has pioneered One Health initiatives in over 45 countries and has worked to reduce the impact of diseases such as Ebola, measles and tuberculosis on humans and animals including gorillas and chimpanzees. Executive Vice President for Health and Policy at EcoHealth Alliance, Karesh is also president of the World Organisation for Animal Health Working Group on Wildlife and an expert on the World Health Organization (WHO)'s International Health Regulations Roster of Experts focused on the human–animal interface and wildlife health. Author of over 200 peer-reviewed articles and numerous book chapters, he received a Bachelor of Science in biology from Clemson University in South Carolina, United States of America in 1977, and a doctorate in veterinary medicine from the University of Georgia, South Carolina in 1982.

KARESH
ECOHEALTH ALLIANCE
ONE HEALTH

100 DAYS AGENDA





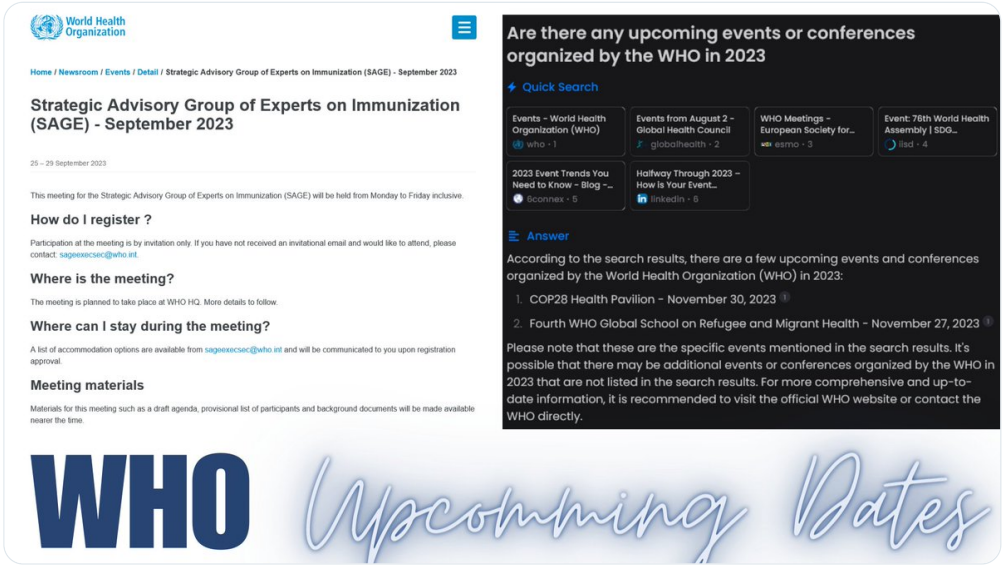
19🧵I haven't even begun on the Disease Surveillance apparatus that they are trying to implement globally and how all these people are names you WILL see again in regards to your health freedoms. Receipts are on the slides. #NoOneHealth #stopthetreaty

EIOS = EPIDEMIC INTELLIGENCE FROM OPEN SOURCES
WHO=WORLD HEALTH ORGANIZATION
HDRAS = HAZARD DETECTION AND RISK ASSESSMENT
JRC=JOINT RESEARCH CENTRE
EAR=EARLY ALERTING AND REPORTING
EC=EUROPEAN COMMISSION
WOAH=WORLD ORGANIZATIONF FOR ANIMAL HEALTH
PAHO= PAN AMERICAN HEALTH ORGANIZATION
GPHIN= GLOBAL PUBLIC HEALTH INTELLIGENCE NETWORK
GHIF= GLOBAL HEALTH INVESTMENT FUND [2012]
GHIC=GLOBAL HEALTH INVESTMENT CORPORATION
GHSA-GLOBAL HEALTH SECURITY AGENDA
GPMB-GLOBAL PREPAREDNESS MONITORING BOARD
IAVI- INTERNATIONAL AIDS VACCINE INITIATIVE [1996]
GAVI-GLOBAL ALLIANCE FOR VACCINES AND IMMUNIZATION [2000]
CEPI- COALITION FOR EPIDEMIC PREPAREDNESS INNOVATION [2017]
DHIS2- DISTRICT HEALTH INFORMATION SYSTEM 2 [2006 EU]
HISP= HEALTH INFORMATION SOFTWARE PLATFORM
UN=UNITED NATIONS, USG= UNITED STATES GOV EU=EURO UNION
EC= EUROPEAN COMMISSION

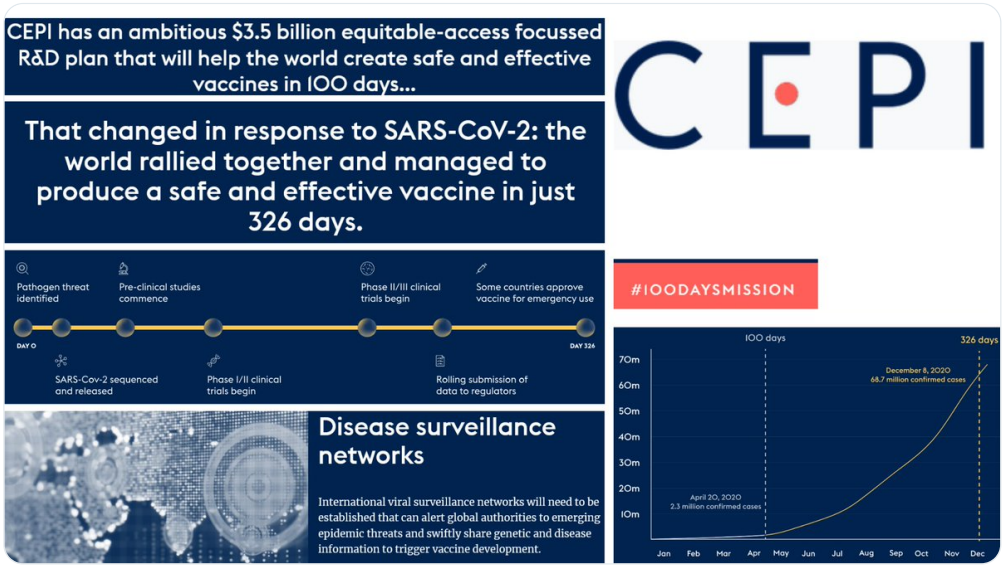
Important

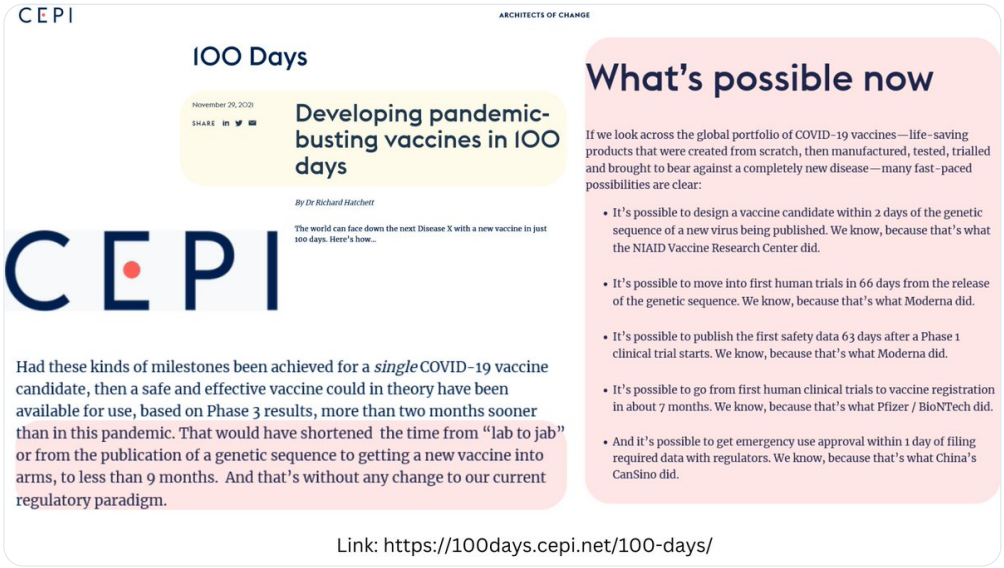
ABBREVIATIONS

that YOU should know !



WHO *Upcomming Dates*





Link: https://100days.cepi.net/100-days/

@carolina_bonita @P_McCulloughMD @US_FDA @NIH @Jikkyleaks @HouseLyndsey @JenLawrence21 @WeAre32937 @jathorpmfm @JeffereyJaxen @7777rep @RandPaul @nic_moneypenny @whitematador @mikemactv @TheRedactedInc @Nuni_Sas_Yu @FrauHodl @Oneiam82 @StealthMedical1

@threadreaderapp unroll this thread

• • •

RESILIENCE BIOTECHNOLOGIES INC.

Company Number	BC1259445
Status	Active
Incorporation Date	30 July 2020 (almost 3 years ago)
Company Type	BC Company
Jurisdiction	British Columbia (Canada)
Business Number	720950070
Registry Page	https://www.orgbook.gov.bc.ca/entity/...

Latest Events

- **2020-07-30** Incorporated

See all events

Corporate Grouping USER CONTRIBUTED

None known. Add one now?

See all corporate groupings

Recent filings for RESILIENCE BIOTECHNOLOGIES INC.

1 Oct 2020 NOTICE OF ALTERATION

Source *OrgBook BC, https://www.orgbook.gov.bc.ca/search, 1 Jul 2023*

Safa'a Al-Rais, Chief Operating Officer at Ontario-based subsidiary Resilience Biotechnologies Inc. (RBI), a subsidiary of National Resilience, Inc. (Resilience), discusses the Canadian Government's CAD 199.2 million ($163.8 million) investment in the site, through the Strategic Innovation Fund. The investment will help increase manufacturing capacity for vaccines and therapeutics, including novel technologies such as mRNA that are being used to fight COVID-19. The expansion will build on RBI's existing strengths as an important biomanufacturing organization in Canada, maintaining 295 existing jobs and create 205 new full-time positions at the Mississauga facility.


May 18, 2021 12:15 PM Eastern Daylight Time

SAN DIEGO & BOSTON--(BUSINESS WIRE)--National Resilience, Inc. (Resilience), a company building the world's most advanced biopharmaceutical manufacturing ecosystem, announced that the Government of Canada will invest CAD 199.2 million ($163.8 million), through the Strategic Innovation Fund, in the company's Ontario-based subsidiary Resilience Biotechnologies Inc. (RBI) to modernize and expand production capacity.

"Resilience was founded during the pandemic to build a better system for manufacturing complex medicines to fight deadly diseases"

Tweet this

This project will help increase manufacturing capacity for vaccines and therapeutics, including novel technologies such as mRNA that are now being used to fight COVID-19. The expansion will build on RBI's existing strengths as an important biomanufacturing organization in Canada, maintaining 295 existing jobs and create 205 new full-time positions at the Mississauga facility.

"Resilience was founded during the pandemic to build a better system for manufacturing complex medicines to fight deadly diseases," said Rahul Singhvi, Sc.D, Chief Executive Officer of Resilience. "This partnership with the Government of Canada will help prepare Canada for future pandemics and strengthen the country's biopharmaceutical ecosystem."

"The Government of Canada's top priority is to protect the health and safety of Canadians. Today's contribution to Resilience Biotechnologies Inc. is another important step to support Canada's leadership in the life sciences sector and to build future pandemic preparedness. These investments are also creating well-paying jobs and helping to grow Canada's life sciences ecosystem as an engine

Resilience Receives USD $164 Million Investment from the Government of Canada to Modernize and Expand Its Ontario Biomanufacturing Site, Improving Pandemic Preparedness

RESILIENCE

NATIONAL RESILIENCE, INC.

- **Headquarters:** San Diego, California, US
- **Website:** www.resilience.com
- **CEO:** Rahul Singhvi
- **Employees:** 1,600
- **Organization:** PRI

Release Summary

Resilience (Durham)

National Resilience manufactures viral vectors, a component of cell and gene therapies.

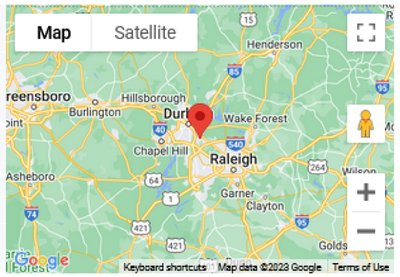
https://resilience.com

1733 T.W. Alexander Drive
Durham NC 27703

Phone (984) 202-0854

County Durham

Region Triangle



Company Details

Company type Bioscience Company	**Year founded** 2020
Employment range in NC 100-199	**US headquarters** California
Global headquarters United States	**Primary site activity** Production and Manufacturing
All company activities Production and Manufacturing	**Core capabilities** Gene Therapy Formulation or Fill and Finish
Potential end market(s) Therapeutics - Gene- and Cell-based Therapies Therapeutics - Large Molecule (biologics) Cancers and other Neoplasms Congenital and Genetic Diseases	

https://bioprocessintl.com › bioprocess-insider › canada-pays-164-million-to-add-resilience

Canada adds Resilience to pandemic prep for $164 - BioProcess .

Canada has called on **Resilience Biotechnologies** to boost local COVID-19 shot capacity. The Canadian Government has given contract development manufacturing organization (CDMO) **Resilience Biotechnologies** $164 million to modernize its recently acquired Ontario plant as par of a wider pandemic preparedness effort.

https://directory.ncbiotech.org › company › resilience-durham

Resilience (Durham) | North Carolina Biotech Center

National Resilience manufactures viral vectors, a component of cell and gene therapies.

https://www.lobbycanada.gc.ca › app › secure › ocl › lrs › do › vwRg?cno=368948

Registration - In-house Corporation - Commissioner of Lobbying ..

In-house Corporation Details Description of activities **Resilience Biotechnologies** (RBI), formerly Therapure Biopharma, is a wholly owned subsidiary of National Resilience, Inc. RBI is an Ontario based Contract Development and Manufacturing Organization (CDMO) specializing in the development and manufacturing of complex biologics.

https://www.theofficialboard.com › news › resilience-biotechnologies

News at Resilience Biotechnologies - The Official Board

Jun 8, 2022 · **Resilience Biotechnologies** has 2,177 competitors including Eurofins (Luxembourg

Resilience Biotechnologies

www.resilience.com

has 25 executives

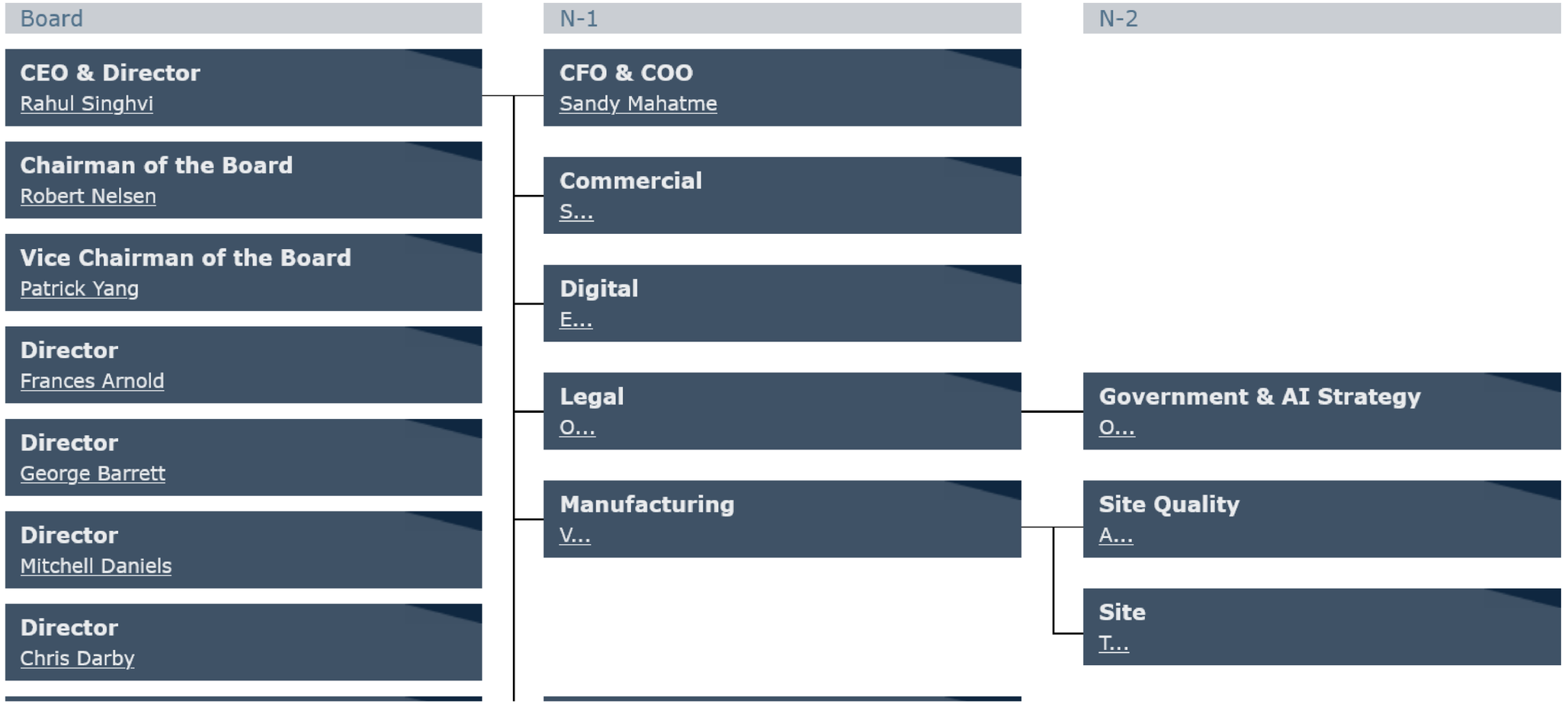
+1 314 527 0579

Add an executive

Resilience Biotechnologies News

Anything missing? We search for you.

Print or download



Links:

https://www.theofficialboard.com/org-chart/resilience-biotechnologies

CISA CYBERSECURITY ADVISORY COMMITTEE

REPORT TO THE CISA DIRECTOR

Technical Advisory Council

Vulnerability Discovery and Disclosure Recommendations

June 22, 2022

Introduction:

The Technical Advisory Council Subcommittee was established to leverage the imagination, ingenu
technical experts from diverse background and experiences for the good of the nation. The subcon
to evaluate and make recommendations tactical and strategic in nature. These Cybersecurity Advis
(CSAC) recommendations for the June Quarterly Meeting focus on vulnerability discovery and discl

CSAC conducted interviews with sector-specific agencies such as the Food and Drug Administration (
vendors, and CISA staff to determine the current state of vulnerability discovery and disclosure practi
government and industry and provide meaningful recommendations

CISA CYBERSECURITY ADVISORY COMMITTEE

Acknowledgements:

Technical Advisory Council Members:

Mr. Jeff Moss, Subcommittee Chair, DEF CON Communications

Mr. Dino Dai Zovi, Security Researcher

Mr. Luiz Eduardo, Aruba Threat Labs

Mr. Isiah Jones, National Resilience Inc.

Mr. Kurt Opsahl, Electronic Frontier Foundation

Receipts

https://cancerletter.com/covid-19-cancer/20210212_4/
https://cen.acs.org/business/outsourcing/Pharmaceutical-services-firm-Resilience-debuts/98/i46
https://ec.europa.eu/commission/presscorner/detail/en/IP_23_3043
https://commission.europa.eu/strategy-and-policy/coronavirus-response_en
https://commission.europa.eu/strategy-and-policy/coronavirus-response/safe-covid-19-vaccines-europeans/eu-digital-covid-certificate_en
https://insmed.com/annual_report/2020/Insmed_2020_AnnualReport.pdf
https://www.lobbycanada.gc.ca/app/secure/ocl/lrs/do/vwRg?cno=368948
https://www.mississauga.com/news/
https://live.worldbank.org/experts/christopher-elias
https://www.gpmb.org/annual-reports/annual-report-2019
https://www.weforum.org/press/2019/10/live-simulation-exercise-to-prepare-public-and-private-leaders-for-pandemic-response
https://www.biotalent.ca/organizations/resilience-biotechnologies/
https://www.cnn.com/2021/11/12/health/covid-cancer-biontech-ugur-sahin/index.html
https://www.fao.org/3/cc1533en/cc1533en.pdf
https://www.gpmb.org/about-us
https://www.gpmb.org/docs/librariesprovider17/default-document-library/gpmb-manifesto-2023.pdf?sfvrsn=f8ac828b_11
Global Health Summit 2021: https://www.youtube.com/live/JWUIMRPgBuQ?feature=share

OrgBook BC

A public directory of organizations registered in BC

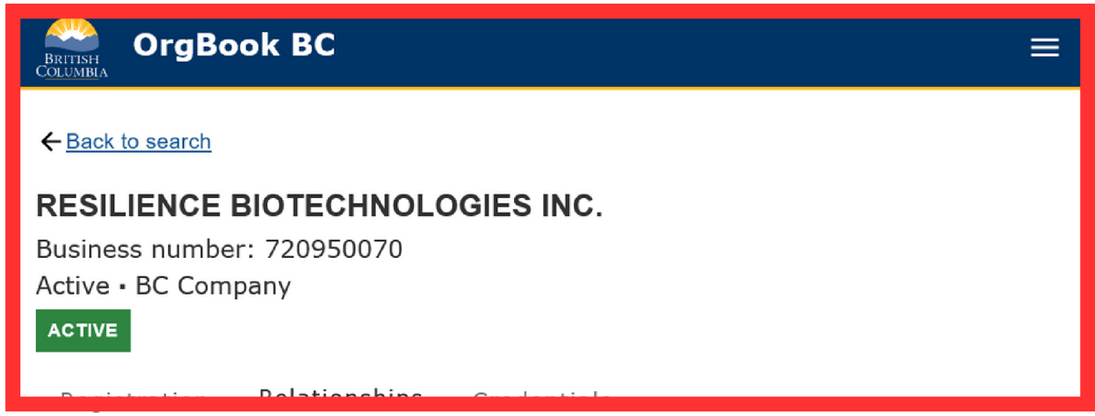
RESILIENCE BIOTECHNOLOGIES INC.

How to search?

Filters

114 result(s)

RESILIENCE BIOTECHNOLOGIES INC.
BC Company
Business number: 720950070
Incorporation number: BC1259445



Show all Credential statuses

Registration

RESILIENCE BIOTECHNOLOGIES INC. is a
BC Company

Incorporation number: BC1259445
Registered on: Jul 29, 2020
Business name effective: Jul 29, 2020

Registration - In-house Corporation

Share this page

Resilience Biotechnologies, Inc. / Sankalp Vashishtha, Vice President / General Manager

Registration Information

In-house Corporation name: **Resilience Biotechnologies, Inc.**
Responsible Officer Name: **Sankalp Vashishtha, Vice President / General Manager**
Responsible Officer Change History
Initial registration start date: **2021-02-24**
Registration status: **Active**
Registration Number: **953057-368948**

Associated Communications

Total Number of Communication Reports: **0**

Monthly communication reports in the last 6 months: **0**

Registration versions: 5 of 5: 2023-02-20 to present

Version 5 of 5 (2023-02-20 to present)

Lobbying Information | **In-house Corporation Details** | **Lobbyists Details**

Description of activities

Resilience Biotechnologies (RBI), formerly Therapure Biopharma, is a wholly owned subsidiary of National Resilience, Inc. RBI is an Ontario-based Contract Development and Manufacturing Organization (CDMO) specializing in the development and manufacturing of complex biologics. RBI's mission is to support for Canadian vaccine and therapeutics production and serve as a long-term partner for Canadian pharmaceutical manufacturing.

Responsible officer name and position during the period of this registration

Sankalp Vashishtha, Vice President / General Manager

Description of activities

Resilience Biotechnologies (RBI), formerly Therapure Biopharma, is a wholly owned subsidiary of National Resilience, Inc. RBI is an Ontario-based Contract Development and Manufacturing Organization (CDMO) specializing in the development and manufacturing of complex biologics. RBI's mission is to support for Canadian vaccine and therapeutics production and serve as a long-term partner for Canadian pharmaceutical manufacturing.

Responsible officer name and position during the period of this registration

Sankalp Vashishtha, Chief Operating Officer, interim

Government funding

End date of the last completed financial year: 2021-12-31

Government Institution	Funding Received in Last Financial Year	Funding Expected in Current Financial Year
National Research Council (NRC)	$2,063,196.23	Yes

In-house Corporation Contact Information

Address:
2585 Meadowpine Blvd.
Mississauga, ON L5N 8H9
Canada

Telephone number: 905-286-6200

Parent Company Information

- National Resilience, Inc.
  - 9310 Athena Circle, Suite 130
    La Jolla, CA 92037
    United States of America

Subsidiary Beneficiary Information

Resilience Biotechnologies, Inc. does not have any subsidiaries that could have a direct interest in the outcome of the undertaking

ORGANIZATION

Therapure Biopharma

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Summary | People | Technology | Signals & News | Similar C

About

Therapure is an integrated Contract Development and Manufacturing Organization.

Acquired by
3SBio Inc.

Mississauga
251-500
Private
www.therapurebio.com/

Highlights

Contacts
54

Employee Profiles
1

Similar Companies
3

Recent News & Activity

News • Aug 11, 2020
PharmiWeb.com — Global Artificial Blood Substitutes Market

Acquisition • Sep 3, 2017
3SBio Inc. acquired Therapure Biopharma for $290,000,000
Discover more acquisitions

Details

Industries
Manufacturing

Founded Date
2008

Operating Status
Active

Company Type
For Profit

Contact Email
info@therapurebio.com

Phone Number
1(905)286-6200

At Therapure Biopharma Inc. they're specialists in biologics therapeutics, and they act on a passion for enhancing patient care through their three divisions: Therapure Biomanufacturing, Therapure Innovations and Therapure Biologics.

Recent News & Activity

Number of Articles
1

News • Aug 11, 2020
PharmiWeb.com — Global Artificial Blood Substitutes Market

Acquisition • Sep 3, 2017
3SBio Inc. acquired Therapure Biopharma for $290,000,000
Discover more acquisitions

M&A Details

Therapure Biopharma was acquired by 3SBio Inc. for $290M on Sep 3, 2017.

Transaction Name
Therapure Biopharma acquired by ...

Acquired by
3SBio Inc.

Announced Date
Sep 3, 2017

Price
$290M

3SBio Inc.

Summary | Financials | People

Details

Industries
Biotechnology

Headquarters Regions
Asia-Pacific (APAC)

Founded Date
1993

Founders
Dr. Jing Lou

Operating Status
Active

Last Funding Type
Post-IPO Equity

Legal Name
Sunshine Guojian Pharmaceuticals (Shanghai) Co., Ltd.

Stock Symbol
NASDAQ:SSRX

Company Type
For Profit

Number of Exits
1

Phone Number
+862425386000

3SBio is a fully integrated, profitable biotechnology company focused on researching, developing, manufacturing and marketing biopharmaceutical products primarily in China. Its focus is on addressing large markets with significant unmet medical needs in nephrology, oncology, supportive cancer care, inflammation and infectious diseases.With headquarters and GMP-certified manufacturing facilities in Shenyang, PRC, 3SBio employs over 800 people.

Frequently Asked Questions

Where is **3SBio Inc.**'s headquarters? **3SBio Inc.** is located in **Shenyang, Liaoning, China**.

Who invested in **3SBio Inc.**? **3SBio Inc.** is funded by **Numab**.

How much funding has **3SBio Inc.** raised to date? **3SBio Inc.** has raised **CHF15M**.

When was the last funding round for **3SBio Inc.**? **3SBio Inc.** closed its last funding round on **Dec 12, 2019** from a **Post-IPO Equity** round.

Who are **3SBio Inc.**'s competitors? Alternatives and possible competitors to **3SBio Inc.** may include **Brainsway**, **Innovative Cellular Therapeutics**, and **MabSpace Biosciences**.

Resilience Biotechnologies Inc.

(0 Reviews)

1733 TW Alexander Dr
Durham, NC 27703

Header	Company	Date	News Type
Proposed Initial Public Offering			
Therapure Biopharma Launches Biologics Division as Evolve Biologics, an Innovative Plasma-Derived Therapeutics Company	Evolve Biologics Inc. Resilience Biotechnologies Inc.	2018-03-23	Financial News
Therapure Biopharma Inc. Wins the Mississauga Board of Trade's 2017 Business Awards of Excellence	Resilience Biotechnologies Inc.	2017-11-17	Other Company News
Therapure Biopharma Inc. Ranks No. 115 on the 2017 PROFIT 500 – Its 4th Consecutive Year on the List	Resilience Biotechnologies Inc.	2017-09-27	Other Company News
3SBio Accelerates Expansion of Its Global Biologics Platform by Acquiring the Canadian Biomanufacturing Business of Therapure	3SBio Inc. CPE Funds Resilience Biotechnologies Inc.	2017-09-03	Financial News
Therapure Biomanufacturing Receives 2017 CMO Leadership Individual Attribute Awards for Capabilities and Staff Characteristics	Resilience Biotechnologies Inc.	2017-04-05	Other Company News
For a Third Consecutive Year Therapure Biopharma Inc. Ranks in the PROFIT 500 List of the Fastest-Growing Companies in Canada and Ranks 10th in the GTA Manufacturing Sector	Resilience Biotechnologies Inc.	2016-09-30	Other Company News

Company News

Company Resilience Biotechnologies Inc.

Company News

Header	Company	Date	News Type
U of T Home to New Hub That Will Strengthen Canada's Pandemic Preparedness and Increase Biomanufacturing Capacity	Centre for Commercialization of Regenerative Medicine adMare BioInnovations CoVaRR-Net Cyclica Inc. Cytiva National Research Council Canada Providence Therapeutics Holdings Inc. Resilience Biotechnologies Inc. Sanofi SA Sartorius Stedim Biotech S.A. University of Saskatchewan University of Toronto	2023-03-02	Financial News
Evolve Biologics Announces Site Selection, Land Purchase and Groundbreaking Ceremony for First Manufacturing Facility in Sachse, Texas	Evolve Biologics Inc. National Resilience, Inc. Resilience Biotechnologies Inc.	2021-12-06	Product News
Resilience Receives USD $164 Million Investment From the Government of Canada to Modernize and Expand Its Ontario Biomanufacturing Site, Improving Pandemic Preparedness	National Resilience, Inc. Resilience Biotechnologies Inc. Strategic Innovation Fund (SIF)	2021-05-18	Financial News

CURES ACT Provisions:

MCM-specific Cures provisions

In addition, the Cures Act included MCM-specific provisions (Subtitle H). Among other things, these sections include provisions (1) to waive certain requirements of the Paperwork Reduction Act during a public health emergency, (2) to streamline BARDA's procurement processes, and (3) for BARDA to enter into an agreement with an independent, nonprofit entity to support MCM development.

There are two FDA-specific MCM provisions:

EUA authority

First, section 3088 of the Cures Act amends FDA's Emergency Use Authorization (EUA) authority (section 564 of the FD&C Act) to permit EUAs that:

1. Authorize emergency use of unapproved animal drugs or unapproved uses of approved animal drugs,
2. Make applicable other emergency use authorities (e.g., to issue emergency dispensing orders, waive compliance with Current Good Manufacturing Practices, make available CDC Emergency Use Instructions, and extend expiration dates) to approved animal drugs, and
3. Allow unapproved animal drugs to be held for emergency use.

Although the FDA's guidance Emergency Use Authorization of Medical Products and Related Authorities (2017) does not specifically reference animal drugs, its recommendations apply to this new authority. FDA intends to address any novel questions or issues over time as we develop more experience with animal drug EUAs.

Chris Elias
President, Global Development at Bill & Melinda Gates Foundation

Experience

President, Global Development
Bill & Melinda Gates Foundation
Feb 2012 - Present · 11 yrs 6 mos

The Bill & Melinda Gates Foundation's Global Development Division works to identify and fund high-impact solutions that can help hundreds of millions of people lift themselves out of ...see more

President and CEO
PATH
2000 - Jan 2012 · 12 yrs 1 mo

For more than a decade, I served as president and CEO of PATH, an international nonprofit organization dedicated to improving the health of people around the world. At PATH, I ex ...see more

Senior Associate, International Programs
Population Council
1990 - 2000 · 10 yrs

As a senior associate, I oversaw all Population Council activities in Thailand, Cambodia, Myanmar, Yunnan, and the Lao PDR, encompassing reproductive health programs, interventions res ...see more

Interests

Top Voices | Companies | Schools

Peter Sands · 3rd
Executive Director at The Global Fund to Fight AIDS, Tuberculosis and Malaria

Bill Gates
Co-chair, Bill & Melinda Gates Foundation
34,786,737 followers

Christopher Elias

President, Global Development Programs, Gates Foundation

Featured on: April 17, 2015

Dr. Elias has been in this role since 2011. He is responsible for all activities outside of the U.S. that are not focused on new medicine development Dr. Elias oversees Global Development's portfolio in Agriculture Development; Family Planning; Financial Services for the Poor; Maternal, Newborn, & Child Health; Polio; Vaccines Delivery; Water, Sanitation & Hygiene; and Special Initiatives. Previously he served as President/CEO of PATH, an international nonprofit organization dedicated to improving the health of people around the world by advancing technologies, strengthening systems, and encouraging healthy behaviors. Elias currently serves on various advisory boards, including the Nike Foundation and the Duke Global Health Institute. Dr. Elias holds an MD from Creighton University, having completed postgraduate training in internal medicine at the University of California San Francisco, and an MPH from the University of Washington. medicine) from Creighton/UCSF, MPH from University of Washington.

Pharmaceutical services firm Resilience debuts, with questions

New company pitches itself as a disruptive engineering services firm in biopharmaceutical manufacturing

by ***Rick Mullin***

November 25, 2020 | A version of this story appeared in **Volume 98, Issue 46**

Resilience, a venture-backed biopharmaceutical manufacturing services firm, has made its debut with an announcement of $800 million in the bank, a roster of highly-accomplished leaders, and an intent to develop “powerful new technologies” that will define the future of therapeutics.

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4 new chemical technolo could make an impact

Is ammonia the fuel of th future?

As a first step, Resilience has acquired Therapure Biopharma, a biologics services firm in Mississauga, Ontaro, that observers say has been for sale for 3 years. It also purchased an undisclosed protein-based therapy-manufacturing operation in the US, Resilience CEO Rahul Singhvi says. Both deals were closed in October.

In addition, Singhvi says the firm has laboratory space in place in San Diego and a pending deal for lab space in Boston. The company plans to add two more manufacturing sites to its network in 2022. Resilience plans to establish a network of approximately 10 facilities with expertise in biological drug development, says Singhvi, former CEO of the vaccine maker Novavax.

RESILIENCE GOVERNMENT SERVICES, INC BRANCH

Company Number	F16440265
Status	Incorporated
Incorporation Date	31 March 2015 (over 8 years ago)
Company Type	FOREIGN CORPORATION
Jurisdiction	Maryland (US)
Branch	Branch of OLOGY BIOSERVICES, INC. (Delaware (US))
Registered Address	13200 NW NANO COURT ALACHUA 32615 FL United States
Previous Names	NANOTHERAPEUTICS, INC OLOGY BIOSERVICES, INC
Business Classification Text	03 ORDINARY BUSINESS - STOCK
Agent Name	CSC-LAWYERS INCORPORATING SERVICE
Agent Address	CSC-LAWYERS INCORPORATING SERVICE, COMPANY, 7 ST. PAUL STREET, SUITE 820, BALTIMORE, MD, 21202
Directors / Officers	CSC-LAWYERS INCORPORATING SERVICE, agent
Registry Page	https://egov.maryland.gov/BusinessExp...

Recent filings for RESILIENCE GOVERNMENT SERVICES, INC

Latest Events

- **2022-05-01 - 2022-05-31** Change of name from 'OLOGY BIOSERVICES, INC.' to 'RESILIENCE GOVERNMENT SERVICES, INC.'
- **2022-09-01 - 2022-09-30** Change of name from 'RESILIENCE GOVERNMENT SERVICES, INC.' to 'RESILIENCE GOVERNMENT SERVICES, INC'
- **2022-09-01 - 2022-09-30** Change of name from 'RESILIENCE GOVERNMENT SERVICES, INC.' to 'RESILIENCE GOVERNMENT SERVICES, INC'

See all events

Corporate Grouping USER CONTRIBUTED

None known. Add one now?

See all corporate groupings

Similarly named companies

branch **RESILIENCE GOVERNMENT SERVICES, INC.** *(Florida (US), 19 Jun 2009-)*

branch **RESILIENCE GOVERNMENT SERVICES, INC.** *(California (US), 22 Mar 2017-)*

and Common Agreement to Support Advancing Nationwide Interoperability of Electronic Health Information

The Office of the National Coordinator for Health Information Technology (ONC) today announced that The Sequoia Project has been awarded a cooperative agreement to serve as the Recognized Coordinating Entity (RCE). The RCE will be responsible for developing, updating, implementing, and maintaining the Common Agreement component of the Trusted Exchange Framework and Common Agreement (TEFCA). The Common Agreement will create the baseline technical and legal requirements for health information networks to share electronic health information and is part of ONC's implementation of the 21st Century Cures Act (Cures Act).

"The Sequoia Project was selected through a competitive process to help with the interoperable flow of health information. We look forward to working in close collaboration with The Sequoia Project and across the broader health system to create a Common Agreement that best serves the needs of all stakeholders," said Don Rucker, MD, National Coordinator for Health Information Technology.

In the Cures Act, Congress directed HHS to advance trusted exchange of electronic health information among health information networks through the Trusted Exchange Framework and Common Agreement. The Cures Act's focus on trusted exchange is an important step toward fostering transparency and competition throughout the healthcare delivery system by addressing the technical barriers and business practices that impede the secure and appropriate sharing of electronic health information.

In addition to the Common Agreement, the RCE will collaborate with ONC to designate and monitor